510(k) Submission Strategy Report

CardioView Handheld Ultrasound System

Executive Summary

The CardioView Handheld Ultrasound System is a portable cardiac ultrasound device indicated for obtaining and displaying ultrasonic images and data for viewing, analysis, and diagnosis of the heart and blood vessels in adult and pediatric patients in hospital, clinic, and point-of-care settings. This report provides a comprehensive 510(k) submission strategy including predicate device analysis, product code determination, required testing programs, and Pre-Submission meeting objectives.

Primary Recommendation: Pursue Traditional 510(k) pathway with **K232808 (Butterfly iQ3 Ultrasound System)** as the primary predicate device, supplemented by **K202406 (Butterfly iQ Ultrasound System)** as a reference predicate.

Key Strategic Considerations:

- Product Code: **IYN** (Ultrasonic Pulsed Doppler Imaging System) - Primary
- Regulatory Class: **Class II**
- Estimated Review Time: 90-120 days based on predicate review times
- Clinical Studies: **Not expected to be required** based on predicate comparison
- Pre-Submission (Q-Sub) Meeting: **Strongly Recommended**

---

1. Predicate Device Analysis

1.1 Potential Predicate Devices

K Number	Device Name	Manufacturer	Product Code	Clearance Date	Review Days	Description
K232808	**Butterfly iQ3 Ultrasound System**	**Butterfly Network, Inc.**	**IYN, IYO, ITX, QIH**	**01/04/2024**	**114**	**Portable handheld ultrasound with cardiac indications**
K220068	Butterfly iQ/iQ+ Ultrasound System	Butterfly Network, Inc.	IYN, IYO, ITX, QIH	03/31/2023	445	Portable handheld ultrasound with cardiac indications

K Number	Device Name	Manufacturer	Product Code	Clearance Date	Review Days	Description
K202406	Butterfly iQ Ultrasound System	Butterfly Network, Inc.	IYN, IYO, ITX	09/16/2020	26	Portable handheld ultrasound with cardiac indications
K242681	NUSONO Handheld Ultrasound Scanner	NURODATA INC.	IYN	02/20/2025	167	Portable handheld general ultrasound
K251481	ACUSON Sequoia Diagnostic Ultrasound System	Siemens	IYN	08/20/2025	99	Cart-based ultrasound with cardiac capabilities

1.2 Recommended Primary Predicate: K232808 - Butterfly iQ3 Ultrasound System

Device: Butterfly iQ3 Ultrasound System
510(k) Number: K232808
Clearance Date: January 4, 2024
Manufacturer: Butterfly Network, Inc.
Product Codes: IYN (Primary), IYO, ITX, QIH (Secondary)

Indications for Use:

The iQ3 Ultrasound System is indicated for use by qualified and trained healthcare professionals to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications:

- Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies)
- Small Organs (including thyroid, scrotum and breast)
- **Cardiac**
- Abdominal
- Lung
- Procedural Guidance
- Urology
- Fetal/Obstetric
- Gynecological
- Musculoskeletal (conventional)
- Musculoskeletal (superficial)
- Ophthalmic

Modes of Operation: B-mode, B-mode + M-mode, B-mode + Color Doppler, B-mode + Power Doppler, Spectral Pulsed Wave Doppler, Fetal Heart Sounds, B-mode + Biplane, B-mode + Needle Viz Tool, B-mode + Biplane + Needle Viz Tool, B-mode + Multi-Slice, and B-mode + Sweep

Settings: Professional healthcare facilities (e.g., hospital, clinic, hospice, or medical office), home healthcare environment, ambulances and/or accident sites, and other environments where healthcare is provided

Key Technologies:

- **Portable handheld form factor** - single transducer design
- **Capacitive Micromachined Ultrasonic Transducer (CMUT) array** rather than traditional piezoelectric technology
- **Frequency Range:** 1.0-12 MHz
- **Connection:** USB cable to commercial off-the-shelf (COTS) mobile device (iOS/Android)
- **Battery operated** for portability
- **Multiple imaging modes** including Doppler capabilities for cardiac assessment
- **Point-of-care use** in diverse healthcare settings

Testing Performed (from 510(k) Summary):

- **IEC 60601-1 Ed. 3.2** - Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-11 Ed. 2.1** - Home healthcare environment requirements
- **IEC 60601-1-12 Ed. 1.1** - Emergency medical services environment requirements
- **IEC 60601-1-2:2014/AMD1:2020** - Electromagnetic disturbances
- **IEC 60601-2-37 Ed. 2.0** - Particular requirements for ultrasonic medical diagnostic and monitoring equipment
- **ISO 10993-1** - Biological evaluation of medical devices (risk management process)
- **ISO 10993-5** - Tests for in vitro cytotoxicity
- **ISO 10993-10** - Tests for irritation and skin sensitization
- **ISO 14971:2019** - Application of risk management to medical devices
- **Software Verification and Validation** per FDA guidance
- **Acoustic Output** - Meets FDA/AIUM guidelines

Clinical Testing: No clinical studies required to support substantial equivalence

Similarity Assessment to CardioView:

Similarities:

- ✅ **Cardiac indications** included in cleared indications for use
- ✅ **Portable handheld design** for point-of-care use
- ✅ **Adult and pediatric** patient populations
- ✅ **Hospital, clinic, and point-of-care settings**
- ✅ **Multiple imaging modes** including Doppler for cardiac assessment
- ✅ **Class II device** with similar regulatory pathway
- ✅ **Product Code IYN** - Ultrasonic Pulsed Doppler Imaging System
- ✅ **Battery operated** for portability
- ✅ **Digital ultrasound platform** with software-based functionality

Potential Differences to Address:

- 🔶 **Focused cardiac indications** vs. multi-application (CardioView is cardiac-specific)
- 🔶 **Transducer technology** - May differ if CardioView uses piezoelectric vs. CMUT
- 🔶 **Frequency range** - Need to confirm CardioView specifications
- 🔶 **Specific cardiac measurements** - May have cardiac-specific calculation packages
- 🔶 **Display integration** - Connection method and display type

Potential as Primary Predicate: STRONG

Rationale:

1. Most recent clearance (2024) with comprehensive cardiac indications
2. Portable handheld design aligns with CardioView concept
3. Point-of-care setting approval matches intended use
4. Extensive testing program documented and available for reference
5. Successful clearance without clinical studies demonstrates viable pathway
6. Well-established predicate line (Butterfly family) with consistent FDA acceptance

1.3 Reference Predicate: K202406 - Butterfly iQ Ultrasound System

Device: Butterfly iQ Ultrasound System
510(k) Number: K202406
Clearance Date: September 16, 2020
Primary Predicate Used: K163510 (Poseidon Ultrasound System)

This device serves as an excellent reference as it represents the original handheld ultrasound in this family and includes detailed comparison tables and testing protocols that can inform the CardioView submission strategy.

Key Features:

- First FDA-cleared handheld semiconductor-based ultrasound
- Cardiac applications clearly included
- 26-day review time (remarkably fast)
- Established predicate for subsequent iterations

1.4 Additional Reference Devices

K242681 - NUSONO Handheld Ultrasound Scanner

- Recent clearance (February 2025)
- Handheld portable format
- Could provide additional support for handheld ultrasound acceptance
- Product Code: IYN

K251481 - ACUSON Sequoia (Siemens)

- Established cardiac ultrasound platform
- Could reference for cardiac-specific testing protocols
- Traditional cart-based system (less similar form factor)

1.5 Substantial Equivalence Rationale

The CardioView Handheld Ultrasound System is substantially equivalent to K232808 (Butterfly iQ3) based on:

1. **Identical Intended Use:** Diagnostic ultrasound imaging for cardiac assessment in adult and pediatric patients
2. **Similar Technological Characteristics:** Portable handheld ultrasound with Doppler capabilities
3. **Same Fundamental Scientific Technology:** Ultrasonic pulse-echo imaging with Doppler
4. **Equivalent Patient Population:** Adult and pediatric patients
5. **Same Use Environment:** Hospital, clinic, and point-of-care settings
6. **Similar Performance Characteristics:** Real-time 2D imaging with M-mode and Doppler
7. **Same Regulatory Classification:** Class II, Product Code IYN

Key Differentiating Features (Cardiac-Focused):

- CardioView is specialized for cardiac/vascular applications (narrower scope than predicate)
- May include cardiac-specific measurement packages and presets

- Optimized for cardiac imaging workflow

FDA Precedent: The predicate (K232808) demonstrates FDA acceptance of portable handheld ultrasound with cardiac indications. CardioView's cardiac-focused approach represents a **narrowing** rather than expansion of indications, which typically simplifies the substantial equivalence argument.

---

2. Product Code Determination

2.1 Recommended Product Code Classification

Primary Product Code: IYN

- **Classification Name:** Ultrasonic Pulsed Doppler Imaging System
- **Regulation:** 21 CFR 892.1550
- **Class:** Class II (Special Controls)
- **Definition:** A device that combines the features of continuous wave and pulsed wave Doppler devices, providing the ability to produce images of blood flow patterns and to measure blood flow velocities

Why IYN is Appropriate:

1. CardioView includes Doppler capabilities for cardiac blood flow assessment
2. Matches primary product code of recommended predicate (K232808)
3. Aligns with cardiac ultrasound applications requiring flow measurements
4. Most predicates with cardiac indications use IYN as primary code

2.2 Secondary Product Codes to Consider

IYO - Ultrasonic Pulsed Echo Imaging System (21 CFR 892.1560)

- Class II device for producing images of body structures
- May be appropriate if including general 2D cardiac imaging

ITX - Diagnostic Ultrasound Transducer (21 CFR 892.1570)

- Class II device that converts electrical energy into ultrasonic energy
- Applicable to the transducer hardware component

QIH - Medical Image Management and Processing System (21 CFR 892.2050)

- Class II device for managing and processing medical images
- May be relevant if including advanced image processing or storage features

2.3 Product Code Strategy

Recommended Approach:

- Submit under **IYN as primary** product code
- Include **IYO and ITX as secondary** product codes to match predicate structure
- Consider **QIH** if CardioView includes significant image management features

Rationale: This multi-code approach matches the successful strategy used by Butterfly Network and provides comprehensive coverage of device functionality while maintaining clear primary classification for cardiac Doppler imaging.

---

3. Required Testing Program

3.1 Performance Testing Overview

Based on the predicate device (K232808) and FDA guidance document "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" (February 2023), the following testing program is recommended:

3.2 Electrical Safety and Performance Testing

3.2.1 Basic Safety Standards

IEC 60601-1 Edition 3.2 (2020)

- **Purpose:** General requirements for basic safety and essential performance
- **Rationale:** Required for all medical electrical equipment
- **Key Tests:**
  - Electrical safety (leakage currents, protective earth, insulation)
  - Mechanical safety
  - Protection against excessive temperatures
  - Protection against mechanical hazards
  - Protection against unwanted radiation
  - Protection against ignition of flammable anesthetic mixtures
  - Essential performance testing
- **Acceptance Criteria:** Must meet all requirements; no deviations from standard

IEC 60601-1-2:2014/AMD1:2020

- **Purpose:** Electromagnetic compatibility (EMC) - emissions and immunity testing
- **Rationale:** Required to demonstrate the device will not interfere with other equipment and will operate in electromagnetic environments
- **Key Tests:**
  - Radiated emissions (conducted and radiated)
  - Immunity testing (ESD, radiated RF, conducted RF, electrical fast transients, surge, voltage dips)
- **Acceptance Criteria:** Device must meet Group 1 Class B emission limits; must maintain essential performance during immunity testing

IEC 60601-1-11 Edition 2.1 (2020) - If applicable for home use

- **Purpose:** Requirements for medical electrical equipment in home healthcare environment
- **Rationale:** Required if CardioView is intended for home healthcare use
- **Key Tests:**
  - Usability in home environment
  - Instructions for lay operators (if applicable)
  - Home-specific safety considerations
- **Acceptance Criteria:** Compliance with all requirements if home use is claimed

IEC 60601-1-12 Edition 1.1 (2020) - If applicable for emergency use

- **Purpose:** Requirements for emergency medical services environment
- **Rationale:** Required if CardioView is intended for emergency/ambulance use
- **Key Tests:**
  - Ruggedness for transport and use in ambulances
  - Environmental conditions (vibration, shock, temperature extremes)
  - Battery performance in emergency conditions
- **Acceptance Criteria:** Compliance with all requirements if emergency use is claimed

3.2.2 Ultrasound-Specific Standards

IEC 60601-2-37 Edition 2.0 (2007) + AMD1:2015

- **Purpose:** Particular requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- **Rationale:** Core standard for all diagnostic ultrasound devices
- **Key Tests:**

    - Acoustic output measurements and reporting per FDA guidance
    - Thermal index (TI) and mechanical index (MI) calculations
    - Maximum acoustic output levels per FDA/AIUM guidelines
    - Transducer heating tests
    - Image quality and resolution verification
    - Measurement accuracy verification
    - Operational accuracy of controls and displays
- **Acceptance Criteria:**
    - MI and TI values must not exceed FDA Track 3 limits OR must comply with Track 1/2 if within IEC limits
    - Must meet FDA Output Display Standard requirements
    - All safety and performance requirements met

NEMA UD-2:2004 Rev 3 (or later)

- **Purpose:** Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- **Rationale:** FDA-recognized standard for measuring and reporting acoustic output
- **Key Tests:**
    - Peak rarefactional pressure measurements
    - Spatial peak temporal average intensity (ISPTA)
    - Spatial peak pulse average intensity (ISPPA)
    - MI and TI calculations per standard methodology
- **Acceptance Criteria:** Accurate measurements per standard; proper reporting in 510(k) and labeling

NEMA UD-3:2004 (or later)

- **Purpose:** Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices
- **Rationale:** Required for on-screen display of safety indices
- **Key Tests:**
    - Verification of TI and MI display accuracy
    - Display updates in real-time during operation
    - Display visibility and location per standard
- **Acceptance Criteria:** TI and MI displayed accurately and updated in real-time; visible to operator

3.3 Biocompatibility Testing

ISO 10993-1:2018

- **Purpose:** Biological evaluation of medical devices - Evaluation and testing within a risk management process
- **Rationale:** Required for all devices with patient contact
- **Testing Matrix:** Based on contact type (surface contact), duration (limited), and tissue type (intact skin, potentially mucous membranes)

Required Biocompatibility Tests (per ISO 10993-1 matrix):

ISO 10993-5 - Cytotoxicity

- **Purpose:** In vitro tests for cell viability/toxicity
- **Rationale:** Baseline biocompatibility assessment for patient-contacting materials
- **Method:** Extract or direct contact testing with cells
- **Acceptance Criteria:** No cytotoxic response (cell viability >70%)

ISO 10993-10 - Irritation and Sensitization

- **Purpose:** Assess potential for skin irritation and allergic sensitization
- **Rationale:** Required for devices with skin contact
- **Tests:**
  - Skin irritation (Primary Skin Irritation or Modified Draize test)
  - Skin sensitization (Guinea Pig Maximization Test or Local Lymph Node Assay)
- **Acceptance Criteria:**
  - Irritation: Primary Irritation Index (PII) ≤ 2.0 (mild or less)
  - Sensitization: No sensitization response

Additional Tests if Applicable:

ISO 10993-18 - Chemical Characterization

- If novel materials are used or extractables/leachables assessment needed

ISO 10993-23 - Irritation (Extended)

- If extended or chronic contact is anticipated

Material Safety Data:

- For known materials (medical-grade polymers), may rely on material supplier biocompatibility data
- Must demonstrate materials are equivalent to those used in cleared predicates

3.4 Software Verification and Validation

FDA Guidance: Content of Premarket Submissions for Software Contained in Medical Devices (2005)

Level of Concern: Likely **Moderate** (imaging device used for diagnosis but with physician oversight)

Required Documentation:

1. **Software Description**
    - Device description and functions
    - Software architecture and design
    - Software development environment
    - Software version control and configuration management
2. **Software Requirements Specification**
    - Functional requirements
    - Performance requirements
    - Interface requirements
    - Security requirements
3. **Software Design Specification**
    - Software architecture diagrams
    - Module/component descriptions
    - Data flow diagrams
    - Database design (if applicable)
4. **Traceability Matrix**
    - Requirements to design
    - Design to test cases
    - Test cases to results
5. **Software Verification Testing**
    - Unit testing
    - Integration testing
    - System testing
    - Regression testing after changes
    - Test coverage analysis

6. **Software Validation Testing**
    - User requirements validation
    - Clinical scenarios testing
    - Usability testing
    - Edge case and stress testing
7. **Software Maintenance Plan**
    - Version control procedures
    - Bug tracking and resolution
    - Update/patch management
8. **Cybersecurity** (per FDA guidance on premarket cybersecurity)
    - Threat modeling
    - Security risk assessment
    - Security controls
    - Software Bill of Materials (SBOM)
    - Vulnerability management plan

IEC 62304:2006/AMD1:2015 - Medical Device Software Life Cycle Processes

- Software development life cycle documentation
- Risk classification and management
- Software maintenance processes

3.5 Mechanical and Environmental Testing

Environmental Conditions Testing:

- **Operating environment:**
    - Temperature: 10°C to 40°C (typical clinical range)
    - Humidity: 30% to 75% RH (non-condensing)
    - Atmospheric pressure: 700 hPa to 1060 hPa
- **Storage and transport:**
    - Temperature: -10°C to 50°C
    - Humidity: 10% to 90% RH (non-condensing)
    - Vibration and shock per IEC 60068-2-6 and IEC 60068-2-27

Mechanical Reliability:

- Drop testing for handheld device (per IEC 60068-2-31 or similar)
- Button/control durability testing
- Transducer cable strain relief testing
- Battery cycle life testing
- Ingress protection testing (if IP rating claimed)

Transducer Performance:

- Element functionality verification
- Transducer check capability (FDA recommendation)
- Image quality consistency over device lifetime
- Sensitivity and resolution measurements

3.6 Battery and Power Management Testing

IEC 62133-2 (if applicable for lithium batteries)

- Battery safety testing
- Overcharge/overdischarge protection
- Thermal runaway prevention

Battery Performance Testing:

- Operational duration on single charge
- Charge/discharge cycle life
- Battery capacity degradation over time
- Low battery warnings and shutdown procedures
- Charging system safety

3.7 Ultrasound Performance Testing

Image Quality Assessment:

- **Spatial Resolution:**
  - Axial resolution measurement
  - Lateral resolution measurement
  - Contrast resolution

    - Test object: Resolution phantoms (e.g., ATS 539, CIRS Model 040GSE)
- **Depth of Penetration:**
    - Maximum imaging depth in cardiac applications
    - Image quality at various depths
    - Test object: Tissue-mimicking phantoms
- **Sensitivity and Dynamic Range:**
    - Minimum detectable signal
    - Dynamic range verification
    - Gray scale reproduction

Doppler Performance Testing:

- **Color Doppler:**
    - Velocity range accuracy
    - Frame rate at various depths
    - Sensitivity to low flow velocities
    - Test object: Doppler flow phantoms (e.g., ATS 707)
- **Spectral Doppler (Pulsed Wave):**
    - Velocity measurement accuracy
    - Aliasing velocity verification
    - Angle correction accuracy
    - Sample volume size and placement
- **M-Mode Performance:**
    - Temporal resolution
    - Motion tracking accuracy

Measurement Accuracy Testing:

- Distance measurements: ±2% or 2mm (whichever is greater) - typical
- Area measurements: ±5%
- Volume calculations: ±10%
- Velocity measurements: ±10% or 2 cm/s (whichever is greater)
- Heart rate calculations: ±2 bpm
- Cardiac function measurements (EF, FS, etc.) - per published standards

Test Methods:

- AIUM 100mm test object
- Tissue-mimicking phantoms
- Doppler flow phantoms
- String targets for resolution

3.8 Usability Testing

IEC 62366-1:2015/AMD1:2020 - Medical devices — Application of usability engineering

Formative Usability Testing:

- Conducted during design phase
- Iterative testing with representative users
- Focus on critical use scenarios and potential use errors

Summative Usability Testing:

- Formal validation with representative users
- Simulated use scenarios covering all critical tasks
- Sample size: Typically 15-25 healthcare professionals
- Pass/fail criteria established for critical tasks

Critical Tasks for Cardiac Ultrasound:

1. Device setup and patient preparation
2. Image acquisition (parasternal, apical, subcostal views)
3. Image optimization (gain, depth, focus adjustments)
4. Doppler interrogation and velocity measurements
5. Cardiac measurements (chamber dimensions, volumes, function)
6. Image storage and documentation
7. Battery management and charging
8. Cleaning and maintenance procedures

User Groups:

- Cardiologists
- Cardiac sonographers
- Emergency medicine physicians

- Critical care physicians
- Residents in training
- (If applicable) Primary care physicians for point-of-care use

3.9 Cleaning and Reprocessing Validation

FDA Guidance: Reprocessing Medical Devices in Health Care Settings (2015)

Required Documentation:

- Validated cleaning instructions
- Disinfection methods and contact times
- Compatible disinfectants (EPA-registered, hospital-grade)
- Reprocessing cycle validation data
- Material compatibility with disinfectants
- Degradation studies after repeated reprocessing

Testing:

- Soil challenge testing with artificial soil
- Residual soil testing after cleaning
- Disinfectant efficacy testing (per EPA guidelines)
- Material degradation testing (100+ cycles minimum)

Bioburden and Sterility (if applicable):

- If device requires sterilization, validation per ISO 11135 (EtO) or ISO 11137 (radiation)
- Likely NOT required for surface-contact diagnostic ultrasound

3.10 Labeling and Human Factors

21 CFR 801.109 - Prescription devices

- Indications for use statement
- Contraindications
- Warnings and precautions
- Instructions for use
- Technical specifications

FDA Guidance Requirements:

- Acoustic output tables and MI/TI display requirements
- Training and credentialing recommendations
- Measurement accuracy specifications and limitations
- Device limitations and conditions of use
- Symbols per IEC 60601-1 and ISO 15223-1

3.11 Risk Management

ISO 14971:2019 - Application of risk management to medical devices

Required Documentation:

- Risk management plan
- Hazard identification and risk analysis
- Risk evaluation and control measures
- Risk/benefit analysis
- Production and post-production information monitoring
- Risk management report

Key Hazards for Cardiac Ultrasound:

- Acoustic bioeffects (thermal, mechanical)
- Electrical shock hazards
- Misdiagnosis due to image artifacts
- Incorrect measurements leading to wrong clinical decisions
- Cybersecurity vulnerabilities
- Battery failure during critical use
- Use by untrained personnel

3.12 Clinical Testing

Recommendation: Clinical studies are **NOT expected to be required** based on predicate comparison with K232808.

Rationale:

- Predicate device (K232808) did not require clinical studies
- CardioView has same fundamental technology and similar indications
- Bench testing and performance data adequate to demonstrate substantial equivalence

- Narrower (cardiac-focused) scope compared to predicate

FDA Precedent: Portable handheld ultrasound devices with cardiac indications have consistently been cleared without clinical studies when:

1. Technological characteristics are similar to cleared predicates
2. Performance specifications meet or exceed predicates
3. Comprehensive bench testing demonstrates safety and effectiveness
4. No novel clinical claims or patient populations

Consider Clinical Studies If:

- Novel imaging modes or measurement algorithms specific to CardioView
- Claims of superiority or enhanced diagnostic accuracy over predicates
- Unique patient population not covered by predicates
- Novel use cases requiring clinical validation
- FDA requests clinical data during Pre-Submission or review

---

4. Pre-Submission (Q-Sub) Meeting Objectives

4.1 Importance of Pre-Submission Meeting

A Pre-Submission meeting is **STRONGLY RECOMMENDED** for the CardioView Handheld Ultrasound System to:

1. Confirm acceptability of proposed predicate device
2. Obtain agreement on product code classification
3. Clarify testing requirements, especially for cardiac-specific features
4. Discuss any novel features or claims
5. Reduce risk of deficiency letters or additional data requests during review
6. Potentially expedite the review process

Timing: Submit Pre-Submission package 3-6 months before planned 510(k) submission

4.2 Recommended Pre-Submission Objectives

Primary Objectives

1. Predicate Device Acceptability

Question: Does FDA agree that K232808 (Butterfly iQ3 Ultrasound System) is an appropriate primary predicate device for demonstrating substantial equivalence of the CardioView Handheld Ultrasound System?

Supporting Information:

- Comparison table highlighting similarities in intended use, technology, and indications
- Explanation of how CardioView's cardiac-focused indications are a subset of K232808's broader indications
- Rationale for why K232808 is most appropriate vs. other potential predicates

Rationale: While we believe K232808 is clearly appropriate, early FDA agreement ensures the submission is built on an acceptable foundation and prevents potential rejection based on predicate selection.

---

2. Product Code Classification Confirmation

Question: Does FDA agree with the proposed product code classification of IYN (Ultrasonic Pulsed Doppler Imaging System) as the primary product code for CardioView, with IYO and ITX as secondary codes?

Supporting Information:

- Description of CardioView's Doppler capabilities
- Justification for IYN based on cardiac flow assessment functionality
- Comparison to predicate product code structure

Rationale: Product code determines regulatory pathway, review division, and applicable standards. Confirming this early prevents misrouting of the submission.

---

3. Testing Protocol Adequacy

Question: Is the proposed testing program (detailed in Section 3) sufficient to demonstrate substantial equivalence and meet FDA expectations for a portable cardiac ultrasound device?

Specific Sub-Questions:

- Are the proposed consensus standards (IEC 60601-1, IEC 60601-2-37, ISO 10993 series) appropriate and sufficient?
- Are there any cardiac-specific performance standards or validation protocols FDA recommends?
- Is the proposed acoustic output testing approach (NEMA UD-2, UD-3) acceptable?
- Are clinical studies required, or is bench testing sufficient given the predicate comparison?

Supporting Information:

- Detailed test plan outline
- Reference to testing performed by predicate
- Proposed acceptance criteria

Rationale: Testing represents the largest development cost and timeline driver. Early agreement on testing requirements prevents costly re-testing and submission delays.

---

4. Indications for Use Statement

Question: Does FDA agree with the proposed Indications for Use statement for CardioView?

Proposed Statement (for discussion): "*The CardioView Handheld Ultrasound System is indicated for use by qualified healthcare professionals in hospital, clinic, and point-of-care settings to obtain and display ultrasonic images and data for viewing, analysis, and diagnosis of the heart and blood vessels in adult and pediatric patients*."

Supporting Information:

- Comparison to predicate's cardiac indications
- Clinical use case descriptions
- User population definition

Rationale: The IFU is the foundation of the 510(k) submission. FDA agreement ensures the statement is appropriately scoped - neither too broad (raising new questions of safety/effectiveness) nor too narrow (limiting commercial utility).

Secondary Objectives

5. Cardiac-Specific Features and Measurements

Question: If CardioView includes cardiac-specific measurement packages (e.g., ejection fraction, fractional shortening, cardiac output calculations), are there specific validation requirements or accuracy specifications FDA expects to see?

Supporting Information:

- List of proposed cardiac measurements
- Proposed accuracy specifications (e.g., EF ±5%)
- Validation methodology (phantoms, clinical correlation studies)

Rationale: Cardiac calculations are clinically important and potential sources of diagnostic error. Understanding FDA's expectations for validation prevents deficiencies related to measurement accuracy.

---

6. Point-of-Care Use Claims

Question: CardioView is intended for point-of-care use in diverse settings (emergency departments, ICU, clinic exam rooms, ambulances). Are there additional human factors or usability testing requirements for point-of-care cardiac imaging beyond standard IEC 62366 compliance?

Supporting Information:

- Description of intended use environments
- User population (cardiologists, emergency physicians, sonographers)
- Proposed usability testing plan

Rationale: Point-of-care use in time-sensitive settings may have unique human factors considerations. FDA has increasing focus on usability for devices used in stressful clinical environments.

---

7. Software and Cybersecurity

Question: Given CardioView's software-based image processing and potential connectivity features, does FDA have specific recommendations for:

- Software validation documentation level (Moderate Level of Concern assumed)
- Cybersecurity documentation per current FDA guidance
- If wireless connectivity is included, any additional testing or validation

Supporting Information:

- Software architecture overview
- Risk classification rationale
- Proposed cybersecurity risk assessment approach

Rationale: Software and cybersecurity are common sources of deficiency letters. Early alignment on documentation expectations prevents delays.

---

8. Comparison to Predicate - Key Differences

Question: CardioView differs from the predicate K232808 in the following ways [list key differences, e.g., cardiac-only indications, specific transducer design, cardiac-optimized workflows]. Do any of these differences

raise questions of safety or effectiveness requiring additional testing or data beyond the standard test program?

Supporting Information:

- Detailed comparison table
- Risk analysis of differences
- Proposed mitigation strategies

Rationale: Proactively addressing differences demonstrates thoroughness and allows FDA to identify any concerns early.

---

9. Regulatory Pathway Confirmation

Question: Based on the totality of information provided, does FDA confirm that the Traditional 510(k) pathway is appropriate, or would FDA recommend a Special 510(k) (same intended use) or Abbreviated 510(k) (guidance/special controls) pathway?

Rationale: While Traditional 510(k) is most likely, confirming the optimal pathway ensures efficient submission preparation.

---

10. Anticipated Review Timeline

Question: Based on similar recent submissions (K232808: 114 days, K202406: 26 days), what is a realistic timeline expectation for CardioView's 510(k) review, and are there opportunities to expedite review (e.g., through complete and well-organized submission)?

Supporting Information:

- Commitment to comprehensive submission
- Availability for interactive review if needed

Rationale: Understanding timeline helps in business planning and resource allocation.

4.3 Pre-Submission Package Contents

Documents to Include:

1. **Pre-Submission Cover Letter**
    - Meeting request and proposed objectives
    - Background on CardioView and company
    - Regulatory history (if any prior FDA interactions)

2. **Executive Summary** (2-3 pages)
    - Device description
    - Intended use
    - Proposed predicate
    - Key questions for FDA
3. **Device Description** (5-10 pages)
    - Detailed technical specifications
    - Comparison to predicate
    - Photographs or renderings
    - Block diagrams
4. **Predicate Comparison Table**
    - Side-by-side comparison of key characteristics
    - Similarities and differences clearly highlighted
5. **Proposed Testing Plan** (10-15 pages)
    - Overview of each test category
    - Standards to be applied
    - Acceptance criteria
    - References to predicate testing
6. **Draft Indications for Use Statement**
7. **Proposed 510(k) Submission Outline**
    - Table of contents for planned submission
    - Demonstrates completeness and organization
8. **Specific Questions List**
    - Organized by priority (primary vs. secondary)
    - Specific, answerable questions

Format: PDF, organized with bookmarks and clear section headers

Timeline: FDA typically schedules Pre-Submission meetings within 75 days; written feedback provided within 60 days

---

4.4 Post-Meeting Actions

After the Pre-Submission meeting:

1. **Incorporate FDA Feedback**
    - Revise testing plan based on FDA recommendations
    - Adjust predicate strategy if FDA suggests alternatives
    - Modify Indications for Use if needed
2. **Document Agreements**
    - Maintain record of FDA's written feedback
    - Reference feedback in 510(k) submission where appropriate
    - Note any agreed-upon deviations from guidance documents
3. **Finalize Development Plan**
    - Update project timeline based on FDA feedback
    - Allocate resources to address any new testing requirements
    - Plan for any additional studies FDA recommends
4. **Prepare for Submission**
    - Complete testing program
    - Compile documentation
    - Plan for potential FDA questions during review

---

5. Regulatory Pathway and Timeline

5.1 Recommended Pathway: Traditional 510(k)

Rationale:

- Device has substantial equivalence to legally marketed predicates
- Well-established predicate with similar technology
- No guidance documents requiring Abbreviated 510(k) pathway
- No split predicates requiring multiple substantial equivalence arguments

5.2 Estimated Timeline

Phase	Duration	Key Activities
Pre-Submission Preparation	2-3 months	Compile device description, predicate comparison, draft questions
Pre-Submission Meeting	2.5 months	FDA schedules meeting (~75 days), provides written feedback

Phase	Duration	Key Activities
Design Finalization	3-6 months	Incorporate FDA feedback, finalize design
Testing Program	6-9 months	Complete all performance, safety, biocompatibility, usability testing
510(k) Compilation	1-2 months	Assemble all documentation, technical writing, quality review
FDA Review	3-4 months	**Target: 90-120 days** based on predicate review times
FDA Questions (if any)	1-2 months	Respond to additional information requests
Clearance	N/A	Receive FDA clearance letter

Total Estimated Timeline: 18-26 months from start to clearance

Critical Path Items:

- Testing program (longest duration)
- FDA Pre-Submission meeting (not flexible timeline)
- FDA review (not controllable, but predictable)

5.3 Opportunities to Expedite

1. **Early Pre-Submission:** Submit Pre-Sub as early as possible to obtain FDA feedback sooner
2. **Parallel Testing:** Conduct testing in parallel where possible (e.g., electrical safety, biocompatibility)
3. **Comprehensive Submission:** Submit complete, well-organized 510(k) to minimize deficiency letters
4. **Interactive Review:** Make Subject Matter Experts available for FDA questions during review
5. **Early Testing:** Begin standard testing (IEC 60601-1, biocompatibility) before Pre-Sub feedback

---

6. Key FDA Guidance Documents

The following FDA guidance documents should be reviewed and followed during development:

1. **Marketing Clearance of Diagnostic Ultrasound Systems and Transducers** (February 2023)
    - Primary guidance for ultrasound device 510(k)s
    - Detailed testing recommendations
    - Acoustic output reporting requirements
    - Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers

2. **Content of Premarket Submissions for Software Contained in Medical Devices** (2005)
    - Software documentation requirements
    - Level of Concern determination
    - Software verification and validation
3. **Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions** (2023)
    - Cybersecurity documentation for connected devices
    - Threat modeling and risk assessment
4. **Applying Human Factors and Usability Engineering to Medical Devices** (2016)
    - Usability testing requirements
    - Human factors validation
5. **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications** (2014)
    - General 510(k) submission requirements
    - Substantial equivalence criteria
6. **Format for Traditional and Abbreviated 510(k)s** (2019)
    - Submission organization and format
    - eCopy requirements
7. **Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling** (2015)
    - Cleaning and disinfection validation requirements
8. **Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process** (2020)
    - Biocompatibility testing framework

---

7. Consensus Standards

The following consensus standards are FDA-recognized and should be followed:

Safety Standards

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 - Medical electrical equipment - General requirements
- IEC 60601-1-2:2014+AMD1:2020 - EMC requirements
- IEC 60601-1-11:2015+AMD1:2020 - Home healthcare environment
- IEC 60601-1-12:2014+AMD1:2020 - Emergency medical services environment
- IEC 60601-2-37:2007+AMD1:2015+AMD2:2020 - Particular requirements for ultrasound equipment

Ultrasound Standards

- NEMA UD-2:2004 (R2009) - Acoustic Output Measurement Standard
- NEMA UD-3:2004 - Real-Time Display of Thermal and Mechanical Acoustic Output Indices
- IEC 62359:2017 - Ultrasonics - Field characterization - Test methods for quality assessment

Biocompatibility Standards

- ISO 10993-1:2018+A1:2020 - Biological evaluation - Risk management
- ISO 10993-5:2009 - Cytotoxicity testing
- ISO 10993-10:2010 - Irritation and sensitization
- ISO 10993-18:2020 - Chemical characterization

Software and Cybersecurity

- IEC 62304:2006+AMD1:2015 - Medical device software lifecycle processes
- IEC 82304-1:2016 - Health software - General requirements for product safety
- AAMI TIR57:2016 - Principles for medical device security—Risk management

Usability

- IEC 62366-1:2015+AMD1:2020 - Usability engineering for medical devices
- IEC 62366-2:2016 - Guidance on application of usability engineering to medical devices

Risk Management

- ISO 14971:2019+A11:2021 - Application of risk management to medical devices

Quality Systems

- ISO 13485:2016 - Medical devices - Quality management systems

---

8. Recommended Next Steps

Immediate Actions (Months 1-3)

1. **Review and Validate Predicate Strategy**
    - ✅ Obtain and thoroughly review K232808 510(k) summary and clearance letter

- ✅ Obtain and review K202406 as reference predicate
- Confirm CardioView's technological characteristics align with predicate comparison
- Document any differences requiring mitigation strategies

2. **Finalize Indications for Use Statement**
    - Draft proposed IFU based on predicate and intended use
    - Ensure cardiac/vascular focus is clearly articulated
    - Define patient population (adult and pediatric)
    - Define use settings (hospital, clinic, point-of-care)
    - Legal and regulatory review of proposed language
3. **Prepare Pre-Submission Package**
    - Compile device description with technical specifications
    - Create detailed predicate comparison tables
    - Draft testing plan based on Section 3 of this report
    - Prepare specific questions for FDA (Section 4)
    - Assemble Pre-Sub documents per Section 4.3
4. **Submit Pre-Submission Request**
    - Submit to FDA via eSTAR (Electronic Submission Template and Resource)
    - Request meeting date and format (teleconference typically sufficient)
    - Allow 75 days for FDA to schedule meeting

Development Phase (Months 4-12)

5. **Initiate Standard Testing** (can begin before Pre-Sub feedback)
    - Electrical safety testing (IEC 60601-1 series)
    - EMC testing (IEC 60601-1-2)
    - Biocompatibility testing (ISO 10993 series)
    - Material characterization
6. **Incorporate Pre-Submission Feedback**
    - Revise development plan based on FDA written feedback
    - Adjust testing program if FDA recommends additional tests
    - Modify design if FDA identifies concerns
7. **Complete Performance Testing**
    - Ultrasound performance testing (IEC 60601-2-37, NEMA UD-2/UD-3)

- Acoustic output measurements and reporting
- Image quality and measurement accuracy validation
- Doppler performance validation
- Battery and environmental testing

8. **Software Validation**
    - Complete software V&V per FDA guidance and IEC 62304
    - Cybersecurity assessment and documentation
    - Perform regression testing after any design changes
9. **Usability Testing**
    - Formative usability studies during design
    - Summative validation study with representative users
    - Document per IEC 62366-1
10. **Risk Management**
    - Maintain risk management file per ISO 14971
    - Update risk analysis as testing is completed
    - Document risk controls and residual risks

Submission Phase (Months 13-15)

11. **Compile 510(k) Submission**
    - Organize per FDA format guidance
    - Complete all sections with comprehensive data
    - Include all test reports, protocols, and results
    - Draft labeling (instructions for use, technical specifications)
    - Prepare cover letter and administrative documents
12. **Internal Review and Quality Check**
    - Technical review by engineering and regulatory teams
    - Quality assurance review of all test reports
    - Regulatory compliance check against FDA guidance
    - Completeness check against Pre-Sub feedback
13. **Submit 510(k) to FDA**
    - Submit via eSTAR
    - Receive acknowledgment letter (FDA has 15 days to assign ID)

- Monitor for Additional Information requests

Review Phase (Months 16-20)

14. **FDA Review Period**
    - Respond promptly to any FDA questions (typically within 10-20 business days)
    - Make SMEs available for teleconferences if FDA requests
    - Track review timeline
15. **Receive Clearance**
    - Obtain clearance letter from FDA
    - Review any conditions or limitations on clearance
    - Plan product launch activities

---

9. Budget and Resource Considerations

Testing Costs (Estimates)

Test Category	Estimated Cost	Timeline
Electrical Safety (IEC 60601-1 series)	$15,000 - $25,000	4-6 weeks
EMC Testing (IEC 60601-1-2)	$20,000 - $35,000	4-6 weeks
Ultrasound Performance (IEC 60601-2-37)	$25,000 - $40,000	6-8 weeks
Biocompatibility (ISO 10993-5, 10993-10)	$10,000 - $20,000	8-12 weeks
Usability Testing	$30,000 - $50,000	8-12 weeks
Environmental & Mechanical	$10,000 - $20,000	4-6 weeks
Total Estimated Testing Costs	**$110,000 - $190,000**	

Regulatory Costs

Activity	Estimated Cost
Pre-Submission User Fee	$0 (free for first Pre-Sub per year)
510(k) User Fee (FY 2024)	$21,485 (standard), $5,371 (small business)

Activity	Estimated Cost
Regulatory Consulting (if used)	$50,000 - $150,000
Technical Writing/Documentation	$30,000 - $60,000

Internal Resources

- **Regulatory Affairs:** 1-2 FTE over 18-24 months
- **Engineering/Design:** 2-3 FTE over 18-24 months
- **Quality Assurance:** 0.5-1 FTE over 18-24 months
- **Software Development:** 2-4 FTE over 18-24 months
- **Clinical/Medical Affairs:** 0.5 FTE over 18-24 months

---

10. Risk Mitigation Strategies

Key Risks and Mitigation

Risk 1: Predicate Device Rejection

- **Mitigation:** Pre-Submission meeting to confirm predicate acceptability
- **Backup Plan:** Identify alternative predicates (K202406, K242681) with strong comparison

Risk 2: Clinical Studies Required

- **Mitigation:** Comprehensive bench testing demonstrating equivalence; Pre-Sub to confirm clinical studies not needed
- **Backup Plan:** Design clinical validation study protocol; allocate budget and timeline

Risk 3: Novel Features Raise New Questions

- **Mitigation:** If CardioView includes novel features, provide robust validation data
- **Backup Plan:** Consider phased approach - initial clearance without novel features, then supplement for additions

Risk 4: Testing Failures

- **Mitigation:** Design for compliance from start; use test houses with ultrasound expertise; conduct pre-testing
- **Backup Plan:** Allocate budget and timeline for design modifications and re-testing

Risk 5: FDA Additional Information Requests

- **Mitigation:** Comprehensive initial submission; anticipate questions and proactively address
- **Backup Plan:** Dedicate resources for rapid response to FDA questions

Risk 6: Software Validation Deficiencies

- **Mitigation:** Follow IEC 62304 rigorously; complete cybersecurity documentation
- **Backup Plan:** Engage software validation consultant if deficiencies received

---

11. Conclusion

The CardioView Handheld Ultrasound System has a **clear and favorable pathway to FDA 510(k) clearance** based on:

1. **Strong Predicate:** K232808 (Butterfly iQ3) provides an excellent predicate with cardiac indications, handheld portability, and recent clearance without clinical studies
2. **Established Technology:** Ultrasound imaging for cardiac applications is well-established with extensive regulatory precedent
3. **Narrower Scope:** CardioView's cardiac-focused indications represent a subset of predicate's broader indications, simplifying substantial equivalence argument
4. **Predictable Testing:** Comprehensive testing program based on recognized standards and predicate device testing
5. **No Clinical Studies Expected:** Based on predicate comparison and FDA precedent for similar devices

Critical Success Factors

✅ **Early Pre-Submission Meeting** - Confirm strategy with FDA before committing to full development
✅ **Comprehensive Testing** - Complete all safety, performance, and usability testing per recognized standards
✅ **Thorough Documentation** - Well-organized, complete 510(k) submission reduces deficiency risk
✅ **Experienced Team** - Regulatory, engineering, and quality resources with medical device experience
✅ **Realistic Timeline** - Allow 18-24 months for development, testing, and FDA review

Expected Outcome

Following the strategy outlined in this report, CardioView has a **high probability of 510(k) clearance** within **90-120 days of submission**, with total time from project start to clearance of approximately **18-26 months**.

The market for portable, point-of-care cardiac ultrasound is growing rapidly, and FDA has demonstrated consistent support for handheld ultrasound innovation through recent clearances. CardioView is well-positioned

to obtain clearance and enter this dynamic market.

Appendix A: Regulatory Contacts

FDA Division: Office of Health Technology 8 (OHT8): Office of Radiological Health
Email: RadHealth@fda.hhs.gov

For Cardiovascular-Specific Questions:
FDA Division: OHT2: Cardiovascular Devices
Phone: 301-796-7000

Division of Industry and Consumer Education (DICE):
Email: DICE@fda.hhs.gov
Phone: 1-800-638-2041 or 301-796-7100

Appendix B: Useful Links

- **FDA 510(k) Database:** https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm
- **FDA Guidance Documents:** https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products
- **FDA Recognized Consensus Standards:** https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- **eSTAR Submission System:** https://www.fda.gov/medical-devices/how-study-and-market-your-device/electronic-submission-template-and-resource-estar
- **FDA User Fee Information:** https://www.fda.gov/medical-devices/premarket-notification-510k/medical-device-user-fee-amendments-mdufa

---

Document Control

Report Prepared By: Regulatory Strategy Team
Date Prepared: January 13, 2026
Version: 1.0
Status: Final

Review and Approval:

- [ ] Regulatory Affairs Review
- [ ] Engineering Review

- [ ] Quality Assurance Review
- [ ] Management Approval

Distribution:

- Regulatory Affairs
- Engineering Team
- Quality Assurance
- Executive Management

This 510(k) submission strategy report is based on publicly available FDA guidance, predicate device information, and regulatory best practices as of January 2026. Regulatory requirements may change, and this report should be updated to reflect current FDA expectations prior to submission. Consultation with experienced regulatory professionals is recommended throughout the development and submission process.