



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 18, 2015

Colibri Technologies Inc.
Sam Mostafavi
Director, Quality And Regulatory
293 Lesmill Road
North York, ON, M3B 2V1 Canada

Re: K151126

Trade/Device Name: Foresight Intracardiac Echocardiography (ICE) System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, ITX
Dated: November 10, 2015
Received: November 17, 2015

Dear Sam Mostafavi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

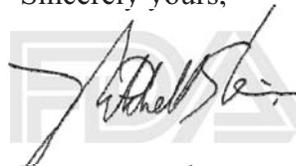
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151126

Device Name

Foresight Intracardiac Echocardiography (ICE) System

Indications for Use (Describe)

The Foresight ICE System is indicated for intracardiac and intraluminal ultrasound visualization of cardiac and great vessel anatomy as well as visualization of other devices in the heart and great vessels of patients. The Foresight ICE System is intended to be used by physicians trained in cardiac catheterization in combination with fluoroscopic imaging and cardiac monitoring equipment with resuscitation equipment readily available.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

510(k) Number: K151126

Applicant Information:

Colibri Technologies Inc.
293 Lesmill Road
North York, ON, M3B 2V1

Contact Person:

Sam Mostafavi
Director of Quality and Regulatory Affairs
Sam.Mostafavi@Colibritech.com
650-670-6972

Date Prepared: November 10, 2015

Device Information:

Name of device: Intracardiac Echocardiography (ICE) System
Trade/Proprietary Name: Foresight Intracardiac Echocardiography (ICE) System
Classification Name(s): Diagnostic Intravascular Catheters, 21 CFR 870.1200 (DQO)
Diagnostic Ultrasonic Transducers, 21 CFR 892.1570 (ITX)
Classification: Class II

Predicate Device:

- K980851 - Boston Scientific Galaxy™ Intravascular Ultrasound Imaging System

Device Description

The Foresight ICE System is an imaging system intended for intracardiac and intraluminal ultrasound visualization of cardiac and greater vessel anatomy. The Foresight ICE System is comprised of a 10.3F sterile, single-use catheter intended to operate with Patient Interface Module (PIM) and the Hummingbird Console.

The Foresight ICE Catheter uses a mechanically scanned single element imaging transducer that allows for both 2D imaging, similar to an existing rotational ICE Catheter, as well as 3D imaging.

The Foresight ICE Catheter is designed to provide ultrasound images of cardiovascular anatomy. It is a mechanically scanning catheter with a single imaging transducer that rotates within the distal end of a deflectable sheath. The distal tip of the sheath is shaped as a dome and made of an acoustically transmissive material (that is also visually transparent). The distal 10 cm of the catheter can be deflected in a single

direction by extending the deflection controller on the handle near the proximal end of the catheter.

The Hummingbird Console is a cart based console that connects to the PIM. It is used to generate and transmit ultrasound imaging energy to activate an ultrasound transducer located at the distal tip of the Foresight ICE Catheter, and then acquire received ultrasound imaging data from the catheter. It then processes imaging data and displays it to the users. It consists of two displays – one for a technician or nurse and one for the physician. It also provides user interfaces for user input.

The PIM serves as the interface between the single-use catheter and the Hummingbird Console. It acts as a relay for electrical ultrasound signals between the Hummingbird Console and catheter. It contains a motor and associated drive system to rotate the transducer imaging assembly of the catheter.

Indications for Use

The Foresight ICE System is indicated for intracardiac and intraluminal ultrasound visualization of cardiac and great vessel anatomy as well as visualization of other devices in the heart and great vessels of patients.

The Foresight ICE System is intended to be used by physicians trained in cardiac catheterization in combination with fluoroscopic imaging and cardiac monitoring equipment with resuscitation equipment readily available.

Comparison of Technological Characteristics with Predicate Device:

Tables below provide a comparison between Colibri Foresight ICE system and Boston Scientific Galaxy™ Intravascular Ultrasound Imaging System, K980851 predicate device:

Catheter comparison Table

Component	Sonicath Ultra 9MHZ (K980851)	Colibri ICE System	Comment
Catheter type	Intracardiac Echocardiography	Intracardiac Echocardiography	Same as Sonicath Ultra 9MHZ (predicate)
Intended use	The UltraICE Rounded Tip Catheter is indicated for enhanced ultrasonic visualization of intracardiac structures.	The Foresight ICE System is indicated for intracardiac and intraluminal ultrasound visualization of cardiac and great vessel anatomy as well as visualization of other devices in the heart and great vessels of patients. The Foresight ICE System is intended to be used by physicians trained in cardiac catheterization in combination with fluoroscopic imaging and cardiac monitoring equipment with resuscitation equipment readily available.	Similar to Sonicath Ultra 9MHZ (predicate). The indication for use for the Colibri ICE system is more similar to that of the AcuNav Diagnostic Ultrasound Catheter (K992631), which itself refers to the same predicate device (K980851).

Outside Diameter	9F Fits inside the recommended Convoy Introducer sheath (with an ID of 8.5F)	10.3 F Fits inside a commercially available 10 F introducer sheath.	Similar to Sonicath Ultra 9 MHz (predicate). Safety and effectiveness is not affected (footnote) ¹ . The 10F AcuNav Diagnostic Ultrasound Catheter (K992631), which itself refers to the same predicate device (K980851), fits inside a commercially available 10F introducer sheath. The UltraICE (Formerly Sonicath Ultra 9MHz) IFU states "The UltraICE Catheter is introduced through a standard 9F (3mm) / 10F (3.3mm) venous or arterial access system."
Imaging energy	Ultrasound	Ultrasound	Same as Sonicath Ultra 9MHz (predicate).
Catheter configuration	Single ultrasound imaging element, mechanically rotated.	Single ultrasound imaging element, mechanically rotated.	Same as Sonicath Ultra 9MHz (predicate).
Ultrasound imaging frequency	9MHz	9MHz	Same as Sonicath Ultra 9MHz (predicate).

¹ a) Bleeding risk:

Manual pressure is the default technique for vascular closure of 9-11F puncture sites for venous access. Catheter sizes larger than 10F are used routinely in clinical practice for venous access, (for example: Niagara Catheter 13.5F) is used for temporary dialysis lines.

b) Fit within the anatomy

The adult cardiovascular anatomy in which the Foresight catheter and UltraICE catheter would be introduced is quite large relative to the size of the catheters themselves. The common femoral vein diameter was assessed in an article by Fronek et al (Journal of vascular surgery May 2001, Volume 33, Issue 5, Pages 1050–1056) and states that for men and women the values are 12.9 mm +/- 1.81mm and 11.2 mm +/- 1.89mm respectively.

Distal end configuration	Rotating imaging core with acoustic window, with soft atraumatic tip (LDPE). The ultrasound imaging transducer has a fixed orientation relative to the longitudinal axis of the catheter.	Rotating imaging core with acoustic window, with soft atraumatic tip (PEBAX 5533). The ultrasound imaging transducer is mounted on a pivot mechanism that allows the transducer to controllably change its orientation relative to the longitudinal axis of the catheter.	Similar to Sonicath Ultra 9MHZ (predicate).
Longitudinal distance from distal tip of catheter to imaging transducer.	Varies – approximately 4-11 mm depending on orientation.	Approximately 1-2 mm.	Similar to Sonicath Ultra 9MHZ (predicate). The reduced distance does not adversely affect the safety and efficacy of the imaging modality. During imaging, the reduced longitudinal distance between the transducer and distal tip of the catheter means that the imaged tissue is in closer proximity to the catheter tip and therefore lessens the uncertainty about when the catheter tip will come into contact with tissue as compared to the predicate device.
Proximal end configuration	Single connector, mechanical snap into motor drive unit.	Single connector, mechanical snap into motor drive unit (referred to as PIM).	Same as Sonicath Ultra 9MHZ (predicate).
Acoustic output	Max pressure: 3.258 MPa	1.61 MPa	Similar to Sonicath Ultra 9MHZ (predicate). The reduced acoustic output reduces risk of tissue bioeffects.

	MI: 1.275	0.57	Similar to Sonicath Ultra 9MHZ (predicate). The reduced acoustic output reduces risk of tissue bioeffects. <i>Note: worst case acoustic output parameters occur for a transducer that is fully forward viewing within the ICE catheter and therefore the autoscanning mode is equivalent to the non-scanning mode under the condition where the steady state motor speed is at maximum.</i>
	PRF: 7.68 KHz	PRF: 5.0 KHz	Similar to Sonicath Ultra 9MHZ (predicate). The reduced acoustic duty cycle reduces risk of tissue bioeffects.
Acoustic testing	As per NEMA UD-2, Rev 1 1993	As per IEC 60601-2-37:2007 and equivalent analysis to NEMA UD-2 performance.	Similar to Sonicath Ultra 9MHZ (predicate).
Sterilization	ISO 11737 (Gamma Irradiation)	ISO 11737 (Ethylene Oxide).	Similar to Sonicath Ultra 9MHZ (predicate).
Imaging modes	B-mode	B-mode	Same as Sonicath Ultra 9MHZ (predicate).
	2D Display: Transducer limited to a fixed orientation ~10 degrees from the full side-viewing position	2D Display: Transducer oriented in a predetermined position that can be set within a range of ~10 degrees from the full side-viewing position to ~10 degrees from the full forward looking position.	Similar to Sonicath Ultra 9MHZ (predicate).
	3D Display: N/A	3D Display: Transducer can be scanned from a start angle to a stop angle within the range of ~10 degrees from the full side-viewing position to ~10 degrees from the full forward looking position.	Similar to Sonicath Ultra 9MHZ (predicate). Maximum acoustic output in 3D mode is the same as for B-mode imaging.

Biocompatibility	ISO 10993, Externally Communicating Device, Circulating Blood category.	ISO 10993, Externally Communicating Device, Circulating Blood category.	Same as Sonicath Ultra 9MHZ (predicate).
Insertable length	110cm; approximately 90 cm usable.	94 cm	Similar to Sonicath Ultra 9MHZ (predicate). Since predicate does not have handle / proximal extension, approximately 20cm or more are required to extend from MDU to entry site.
Catheter construction	Biocompatible Thermopolymer over braided core.	Biocompatible Thermopolymer over braided core.	Same as Sonicath Ultra 9MHZ (predicate).
Re-usability	Single use	Single use	Same as Sonicath Ultra 9MHZ (predicate).
Preparation	Flush with sterile water through distal tip with needle.	Flush with sterile water through luer connector at proximal end.	Similar to Sonicath Ultra 9MHZ (predicate); Improved usability, reduced risk.
Directionality of catheter tip	Instructions for use of the UltraICE catheter recommend the use of a separate multipurpose EP long sheath or guiding catheter to improve the directionality of the catheter tip.	Integrates a tip deflection mechanism using a deflection handle and pullwire to provide integrated control of catheter tip direction.	Similar to Sonicath Ultra 9MHZ (predicate).

Console Comparison Table

Component	Sonicath Ultra 9MHZ (K980851)	Colibri ICE System	Comment
Configuration	Mobile cart with braking system.	Mobile cart with braking system.	Same as Sonicath Ultra 9MHZ (predicate).
Input	Keyboard, trackball and custom interface buttons.	Touchscreen, touchpad, and keyboard.	Similar to Sonicath Ultra 9MHZ (predicate).
Display	Dedicated image display monitor	Dedicated image display monitor, images also displayed on Touchscreen.	Same as Sonicath Ultra 9MHZ (predicate).
Data storage	DICOM	DICOM and native format.	Same as Sonicath Ultra 9MHZ (predicate).
Interface with external systems	Interface to PACS	Interface to PACS	Same as Sonicath Ultra 9MHZ (predicate).
Footprint (centre to centre distance of casters)	580 x 610mm	502 x 502mm	Similar to Sonicath Ultra 9MHZ (predicate).
Peripherals	DVD-ROM, Printer, VHS	DVD-ROM, Printer, USB	Similar to Sonicath Ultra 9MHZ (predicate).
Electrical safety	IEC 60601-1 2nd edition	IEC 60601-1 3rd edition	Similar to Sonicath Ultra 9MHZ (predicate).
Sterile barrier interface	Motor Drive Unit encapsulated in single use disposable sterile bag.	Motor Drive Unit (referred to as Patient Interface Module) encapsulated in single use disposable sterile bag.	Same as Sonicath Ultra 9MHZ (predicate).
Measurements	Depth markers, depth measurements, in plane distance and area measurements.	Depth markers, in plane depth distance measurements.	Similar to Sonicath Ultra 9MHZ (predicate). <i>Note: based on the test results the worst case uncertainty of any depth measurement is +/- 1.2mm.</i>

Impact of 3D imaging capability - The predicate device K980851 (Boston Scientific Galaxy™ Intravascular Ultrasound Imaging System) does not generate 3D reconstructions of anatomy, as it operates with a transducer oriented in a fixed side-viewing position (~10 degrees from the full side-viewing position) while the Colibri Foresight ICE system can vary the transducer orientation from side viewing (~10 degrees from the full side-viewing position) to forward-viewing (~10 degrees from the full forward looking position).

In terms of the intended uses, each of the stated uses is discussed separately below:

1. Therapeutic use: The device does not provide therapy, and thus has no intended therapeutic use.
2. Diagnostic use: While the device does provide visualization of anatomy, it does not claim to diagnose any particular condition. The visualization can be provided in real-time 2D. The 3D imaging capability augments the visualization by reconstructing 2D information into 3D and does not diagnose any conditions. The device can be used as labelled for diagnostic use without 3D reconstruction.
3. Prosthetic use: The device is not a prosthetic, and thus has no intended prosthetic use.
4. Surgical use: The device is not a surgical device, and thus has no intended surgical use.

The 3D capability of the Colibri Foresight ICE System does not affect the substantially equivalency for the determination relative to the 2D system because of the following Safety and Efficacy justifications:

1. Efficacy: Since the Foresight ICE system can achieve approximately the same real-time side viewing angles as the predicate device and can resultantly generate equivalent views, the system is able to provide at least equivalent efficacy in guiding procedures. The ability to tilt the transducer to view at different angles and generate 3D images is supplemental to this B-mode imaging functionality and does not hinder the efficacy.
2. Safety: The acquisition of 3D imagery does not alter the way in which the catheter interacts with the body relative to the predicate:
 - a) 3D images are generated without movement of the catheter, by altering the speed of rotation of the imaging assembly inside the sheath
 - b) The type and intensity of energy deposited to the body is the same or less than the predicate device

By design, the worst case maximum temporal in situ intensity, for the Foresight ICE Imaging System, occurs for the situation where the transducer is in the full forward looking position. This condition has been used to define the worst case B-mode acoustic output and is applicable to both 2D and 3D imaging display modalities. Such a situation would indeed occur for a 3D sweep, provided that the user wanted to include the most forward viewing A-line as part of the intended 3D reconstruction.

The interpretation of 3D reconstructions do not add risk to the patient as users are instructed that the reconstructions need to be considered in light of motion artifacts that may be present due to cardiac motions. Moreover, no measurements of structures in 3D are permitted, nor are length measurements permitted in the real-time 2D images.

Testing completed:

Verification and validation testing was completed in compliance with the following standards:

- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- IEC 60601-1, 3rd edition, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility.
- IEC 60601-1-6, Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability.
- IEC 60601-2-18, Medical Electrical Equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
- IEC 60601-2-37, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility.
- ISO 11135, Second edition 2014, sterile, single-use intravascular catheters - Part 1: General requirements.

Conclusion:

Based upon the Intended Use, Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Colibri Foresight ICE System has shown to be substantially equivalent to the cited predicate device.