DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 28, 2017

Conavi Medical Inc.
Sam Mostafavi
Director of Quality & Regulatory Affairs
293 Lesmill Road
Ontario, CANADA M3B 2V1

Re: K162789
Trade/Device Name: Foresight Intracardiac Echocardiographic (ICE) System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, ITX
Dated: December 15, 2016
Received: December 19, 2016

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162789

Device Name
Foresight Intracardiac Echocardiography (ICE) System

Indications for Use *(Describe)*

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

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K162789

Applicant Information:

Date Prepared:	February 17, 2017
Name:	Conavi Medical Inc.
Address:	293 Lesmill Road North York, ON, Canada M3B 2V1
Contact Person:	Sam Mostafavi Sam@Conavi.com
Mobile Number:	650-670-6972
Office Number:	(416) 483-0100
Facsimile Number:	(416) 483-0101

Device Information:

Trade/Proprietary Name:	Intracardiac Echocardiography (ICE) System
Common 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)
Class:	Class II
Panel:	Division of Cardiovascular Devices

Predicate Device:

- Conavi Medical (Formerly Colibri Technologies) ICE system K151126
- Acuson Corp. AcuNav™ Diagnostic Ultrasound Catheter K992631

Device Description

The Foresight ICE System is intended to be used for real-time, minimally-invasive guidance of several different intracardiac procedures including, but not limited to, atrial ablation procedures and transseptal punctures. The system will provide image information of cardiovascular anatomic features, spatial relationships of other devices within the heart and great vessels, physiological information of cardiovascular structures and features, and intra-procedure complications including pericardial effusions. In doing so we expect to provide an imaging system capable of improving the safety, expediency, cost-effectiveness and patient tolerance of the aforementioned procedures compared to the same procedures using the existing technologies and methodologies.

The system will be comprised of catheter and a cart based console. The console includes the Acquisition and Display Module (ADM) for image display and manipulation as well as the Patient Interface Module (PIM) which the catheter connects to. The ADM will have two monitors to allow for ease of image view and review for both the technician and physician user. The technician user will be able to control the system software via an easy to use interface using multiple methods of input including a mouse, keyboard and/or a touch screen. Casters on the ADM will allow easy movement of the system throughout an EP Lab which can have a small footprint as well as small obstacles to cross.

The catheter will be a 10.3F single use, sterile device, which will be able to perform intracardiac and intraluminal ultrasound imaging of adults. The catheter will be capable of real-time 2D side and forward viewing imaging with the ability to produce rapidly post processed 3D rendered images as well as ECG gated 3D images to reduce motion artifacts. The imaging system will be able to resolve and measure features such as the inferior and superior vena cava, ascending and descending aorta, left and right atria, left and right ventricle, fossa ovalis, aortic valve, mitral valve and tricuspid valves. It will display / measure flow velocities using Color and PW Doppler. The physician user will have easy steering maneuverability of the catheter via deflection and rotation, as well as having control over the position of the transducer to allow for multiple angles of images.

Indications for Use

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

Functional and Technological Comparison

Tables 1 below include functional and technological comparison between the updated Conavi Foresight ICE catheter and market cleared Acuson Corp. AcuNav^{TM} Diagnostic Ultrasound Catheter (K992631).

Tables 2 include functional and technological comparison between the updated Conavi Medical Foresight ICE system and the market cleared Foresight ICE System (K151126).

Table-1: Catheter substantial equivalency comparison

Component	Subject Device	Predicate Devices		Comments
	Conavi ICE System	**Acuson Corporation AcuNav™ (K992631)**	**Colibri ICE System (K151126)**	
Classification	Class II	Class II, 21 CFR §§ 1200 and 892.1570	Class II, 21 CFR §§ 1200	*Same as predicate devices*
Regulation Name	Diagnostic Intravascular Catheter	Diagnostic Intravascular Catheter	Diagnostic Intravascular Catheter	*Same as predicate devices*
Product code	DQO, ITX	DQO, ITX	DQO, ITX	*Same as predicate devices*
Catheter type	Intracardiac Echocardiography	Intracardiac Echocardiography	Intracardiac Echocardiography	*Same as predicate devices*
Clinical performance data	No clinical testing is included in the submission. Determination of substantial equivalence Performance is based on an assessment of non-clinical data.	Human clinical testing is mentioned in the substantial Equivalency discussion, but the study protocol is unknown.	No clinical testing was included in the submission. Determination of substantial equivalence Performance was based on an assessment of non-clinical data.	*Same as predicate device K151126*
Non clinical performance data	Non-clinical data includes bench-top evaluations, animal testing, packaging validation, biological safety, electrical safety, acoustic output testing, and animal testing.	Non-clinical testing includes performance testing, animal testing, human testing, biocompatibility and non-pyrogenic.	Non-clinical data includes bench-top evaluations, animal testing, packaging validation, biological safety, electrical safety, acoustic output testing, and animal testing.	*Similar to predicate devices*

Intended use	The Foresight ICE System is indicated for intracardiac and intraluminal ultrasound visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart and great vessels of patients.	For use directly within the vascular and/or the right heart for intravascular or intracadiac ultrasound imaging. The device is specifically indicated for use in visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart, as well as measurement of blood flow. ventricle The company anticipates that the device will be used for a variety of intravascular and intracardiac imaging applications, consistent with its intended use, including vascular stent placement, monitoring left ventricular function post-surgery; identifying congenital abnormalities before therapeutic procedures; visualizing the relative orientation of diagnostic and therapeutic catheters; and visualizing procedures such as transseptal insertion of other catheters, valvuloplasties, balloon septostomies, septal defect closures, and pacemaker or defibrillator lead insertion or extraction.	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 AcuNav Diagnostic Ultrasound Catheter (K992631)*
Principals of operation	Generation of structural and physiological images / representations / measurements of cardiovascular anatomy using pulse-echo ultrasound systems.	Generation of structural and physiological images / representations / measurements of cardiovascular anatomy using pulse-echo ultrasound systems.	Generation of structural images / representations / measurements of cardiovascular anatomy using pulse-echo ultrasound systems.	*Same as predicate devices*

Outside Diameter	10.3 F Fits inside a commercially available 10 F introducer sheath.	10F	10.3 F Fits inside a commercially available 10 F introducer sheath.	*Similar to the 10F AcuNav Diagnostic Ultrasound Catheter (K992631), which itself refers to the same predicate device (K980851), fits inside a commercially available 10F introducer sheath.*
Imaging energy	Ultrasound	Ultrasound	Ultrasound	*Same as predicate devices*
Catheter configuration	Single ultrasound imaging element, mechanically rotated.	64 Element phased array ultrasound.	Single ultrasound imaging element, mechanically rotated.	*Same as predicate devices*
Ultrasound imaging frequency	9MHz (Center Frequency)	4-10 MHz	9MHz	*Same as predicate device K151126*
Distal end configuration	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 is orientation relative to the longitudinal axis of the catheter.	Static imaging core with rigid phased-array at distal tip.	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 is orientation relative to the longitudinal axis of the catheter.	*Same as predicate device K151126*

Proximal end configuration	Single connector, mechanical snap into motor drive unit (referred to as PIM).	Single connector, mechanical snap into SwiftLink adapter	Single connector, mechanical snap into motor drive unit (referred to as PIM).	*Same as predicate device K151126*
Acoustic output	Max Pressure: 2.55MPa	Not available	Max Pressure: 1.61 MPa	*The increase in max pressure and MI is due to the new modes. However, even in the new modes, acoustic output is below reporting limits and well below diagnostic limits and does not raise new risk*
	MI: 0.93	Not available	MI: 0.57	*The increase in max pressure and MI is due to the new modes. However, even in the new modes, acoustic output is below reporting limits and well below diagnostic limits and does not raise new risk*
Acoustic testing	As per IEC 60601-2-37:2007 and equivalent analysis to NEMA UD-2 performance	As per NEMA UD-2, Rev 1 1993	As per IEC 60601-2-37:2007 and equivalent analysis to NEMA UD-2 performance	*Same as predicate device K151126*

Sterilization	ISO 11135-1:2014 ISO 11138:2006-1 AAMI/ANSI/ ISO 11737-1 (Ethylene Oxide)	ISO 11737 (Ethylene Oxide)	ISO 11737 (Ethylene Oxide)	*Same as predicate devices*
Imaging Modes	B-Mode M-Mode Pulsed Wave Doppler Color Doppler	B-Mode M-Mode Continuous Wave Doppler Pulsed Wave Doppler Color Doppler Power Doppler	B-mode	*Similar to predicate devices*
2D Imaging Configuration	Single element scanning 360 degrees around the catheter. 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.	Phased array limited to ~90 degree sector emanating from the side of the catheter.	Single element scanning 360 degrees around the catheter. 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.	*Same as predicate device K151126*
3D Imaging Configuration	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.	N/A	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.	*Same as predicate device K151126*
Biocompatibility	ISO 10993-7:2008, Externally Communicating Device, Circulating Blood category	ISO 10993, Externally Communicating Device, Circulating Blood category.	ISO 10993, Externally Communicating Device, Circulating Blood category	*Same as predicate devices*
Insertable length	94 cm	90cm	94 cm	*Similar to predicate devices*

Catheter construction	Biocompatible Thermopolymer over braided core	Biocompatible Thermopolymer over braided core.	Biocompatible Thermopolymer over braided core	*Same as predicate derives*
Re-usability	Single use	Single use	Single use	*Same as predicate derives*
Preparation	Flush with sterile water through luer connector at proximal end	No preparation required.	Flush with sterile water through luer connector at proximal end	*Same as predicate device K151126*
Directionality of catheter tip	Integrates a tip deflection mechanism using a deflection handle and pullwire to provide integrated control of catheter tip direction.	Integrates a tip deflection mechanism using a deflection handle and pullwires to provide integrated control of catheter tip direction.	Integrates a tip deflection mechanism using a deflection handle and pullwire to provide integrated control of catheter tip direction.	*Same as predicate devices*

Table-2: Console Comparison Table

Component	Subject Device: Conavi ICE System	Predicate Device: Colibri ICE System (K151126)	Comment
Configuration	Mobile cart with braking system	Mobile cart with braking system	*Same as predicate device*
Input	Touchscreen, touchpad, and keyboard	Touchscreen, touchpad, and keyboard	*Same as predicate device*
Display	Dedicated image display monitor, images also displayed on Touchscreen	Dedicated image display monitor, images also displayed on Touchscreen	*Same as predicate device*
Data storage	DICOM and native format	DICOM and native format	*Same as predicate device*
Footprint (centre to centre distance of casters)	502 x 502mm	502 x 502mm	*Same as predicate device*
Electrical safety	IEC 60601-1 3rd edition	IEC 60601-1 3rd edition	*Same as predicate device*
Sterile barrier interface	Motor Drive Unit (referred to as Patient Interface Module) 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 predicate device*

System: Foresight ICE System
Transducer: Foresight ICE Catheter

Intended Use: Visualization of human anatomy by means of ultrasound imaging:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							

	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P	N	N		N		
	Cardiac Pediatric							
	Intravascular (Cardiac)	P	N	N		N		
	Trans-esoph. (Cardiac)							
	Intra-cardiac	P	N	N		N		
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

For evidence of compliance of the system to guidance provided in Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, please refer to EXT-019. A copy is provided in Appendix 24.8.

Testing completed:

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

1. IEC 60601-1: 2005, + CORR. 1:2006 + CORR. 2:2007 + A1:2012, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
2. IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility.
3. IEC 60601-1-6:2013, Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability.
4. IEC 60601-2-18:2009 in conjunction with IEC 60601-1:2005, Medical Electrical Equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
5. IEC 60601-2-37:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility.
6. ISO 10993-2:2006, Biological evaluation of medical devices – Part 2: Animal welfare requirements.
7. AAMI/ANSI/ISO 10993-7:2008(R) 2012, Biological evaluation of medical devices – Part 7: Ethylene Oxide Sterilization residuals.
8. ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
9. ISO 11135-1:2014, Sterilization of health-care products. Ethylene oxide - Requirements for the development, validation and routine control of sterilization process for medical devices.

Conclusion:

Conavi Foresight ICE System and predicate devices have nearly identical intended use and very similar principles of operational and technological characteristics. The subject device (Conavi Foresight ICE System) and predicate devices are all intended for use in intravascular and/or intracardiac imaging, and the minor technological differences do not raise any new safety and effectiveness risk or concerns. After analyzing the results of bench test, laboratory test, electrical safety test, and animal test, it is the conclusion of Conavi Medical that Conavi Foresight ICE System is safe and as effective for the intended use, is as safe and effective as the predicate devices, and is substantially equivalent to the cited predicate devices.