March 5, 2021

NuVera Medical, Inc.
Robert Nardelli
Vice President, RA/QA
140 Knowles Dr.
Los Gatos, California 95032

Re: K201775
Trade/Device Name: NuVision ICE Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: March 2, 2021
Received: March 3, 2021

Dear Robert Nardelli:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Paulsen
Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201775

Device Name
NuVision ICE Catheter

Indications for Use *(Describe)*
The NuVision ICE Catheter™ is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	K201775
Date Prepared:	June 26, 2020
Applicant Information:	NuVera Medical, Inc 140 Knowles Drive Los Gatos, CA 95032 Registration Number: 3016516752
Contact Person:	Robert Nardelli robert@nuveramedical.com
Office Number:	408-560-2500

Device Information:

Trade/Proprietary Name:	NuVision ICE Catheter
Common Name:	Intracardiac Echocardiography (ICE) Catheter
Classification Name(s):	Diagnostic Intravascular Catheters, 21 CFR 870.1200 (OBJ)
Class:	Class II
Panel:	Division of Cardiovascular Devices
Predicate Device:	AcuNav™ Diagnostic Ultrasound Catheter (K071234)

Device Description

The NuVision ICE Catheter is a diagnostic ultrasound imaging catheter designed for intracardiac use. The catheter can be advanced, retracted and rotated within the anatomy. The catheter is comprised of a 10 Fr outer shaft capable of being rotated and deflected, which houses an ultrasound transducer. The outer shaft rotation is driven directly from a probe knob on the handle, while a deflection knob on the handle drives the deflection by controlling a deflectable inner shaft situated within the outer shaft.

The imaging ultrasound transducer is a 2D piezo-electric array capable of real-time 3D imaging. The imaging field emanates perpendicular to the axis of one side of the imaging tip, also referred to as a probe. The tip movement, in combination with deflection of the distal catheter, provide the user with the ability to adjust the orientation of the imaging tip to visualize the target anatomy.

An electrical connector proximal to the handle allows connection to the NuVision Connector Cable which also connects to an ultrasound cardiac imaging console. Printed circuit boards within the catheter system's electrical connectors help with signal distribution and conditioning. The NuVision ICE Catheter System relies on power from the ultrasound cardiac imaging console to function.

The NuVision ICE Catheter is used with a compatible ultrasound cardiac imaging system with software cleared for market in accordance with 21 CFR 807.81(a)(3).

Indications for Use

The NuVision ICE Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Functional and Technological Comparison

The table below includes a functional and technological comparison between the NuVision ICE Catheter and the market-cleared Siemens AcuNav™ Diagnostic Ultrasound Catheter (K071234).

Table 5-1: Catheter substantial equivalency comparison

Component	Subject Device NuVision ICE Catheter	Predicate Device Siemens AcuNav™ (K071234)	Comments
Classification	Class II	Class II	Same as predicate device
Regulation	21 CFR 870.1200	21 CFR 870.1200	Same as predicate device
Regulation Name	Diagnostic Intravascular Catheter	Diagnostic Intravascular Catheter	Same as predicate device
Product code	OBJ	OBJ	Same as predicate device
Catheter type	Intracardiac Echocardiography	Intracardiac Echocardiography	Same as predicate device
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.	No clinical testing is referenced in the submission.	Same as predicate device
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 data includes bench-top evaluations, animal testing, packaging validation, biological safety, electrical safety, acoustic output testing, and animal testing.	Same as predicate device
Intended use	The NuVision ICE Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	The catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	Same as predicate device
Principles 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.	Same as predicate device
Outside Diameter	10F	10F	Same as predicate device

Component	Subject Device NuVision ICE Catheter	Predicate Device Siemens AcuNav™ (K071234)	Comments
Imaging energy	Ultrasound	Ultrasound	Same as predicate device
Transducer configuration	Multi-element 2D phased array-on-ASIC ultrasound transducer at distal tip.	Multi-element linear phased array ultrasound transducer at distal tip.	Similar to predicate device. Basic transducer technology is the same. The NuVision ICE Catheter 2D array supports 3D imaging.
Ultrasound imaging frequency	4-10 MHz	4-10 MHz	Same as predicate device
Proximal end configuration	Single connector, mechanical snap into NuVision Connector Cable.	Single connector, mechanical snap into SwiftLink adapter	Same as predicate device
Acoustic testing	As per IEC 60601-2-37 and equivalent analysis to NEMA UD- 2 performance	As per IEC 60601-2-37 and equivalent analysis to NEMA UD- 2 performance	Same as predicate device
Sterilization	Ethylene Oxide	Ethylene Oxide	Same as predicate device
Imaging Modes	B-Mode (2D and 3D) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D and 3D) Power Doppler	B-Mode (2D only) M-Mode Doppler Pulsed Wave Doppler Continuous Wave Doppler Color Doppler (2D only) Power Doppler	Similar to predicate device. The NuVision ICE Catheter 2D array supports 3D imaging.
Imaging Configuration	Phased array limited to ~90-degree sector emanating from the side of the catheter.	Phased array limited to ~90-degree sector emanating from the side of the catheter.	Same as predicate device
Biocompatibility	ISO 10993, Externally Communicating Device, Circulating Blood category	ISO 10993, Externally Communicating Device, Circulating Blood category.	Same as predicate device
Insertable length	90 cm	90 cm	Same as predicate device
Catheter construction	Coaxial shafts of biocompatible thermopolymer over braided core	Single shaft of biocompatible thermopolymer over braided core	Similar to predicate device. The NuVision ICE Catheter uses a dual shaft design to allow independent rotation of the catheter tip.

Component	Subject Device NuVision ICE Catheter	Predicate Device Siemens AcuNav™ (K071234)	Comments
Re-usability	Single use	Single use	Same as predicate device
Preparation	No preparation required.	No preparation required.	Same as predicate device
Directionality of catheter tip	Integrates a tip deflection mechanism using a deflection handle and pull-line to provide integrated bidirectional deflection of an inner shaft. Catheter tip is rotated with outer shaft independent of deflection.	Integrates a tip deflection mechanism using a deflection handle and pull-line to provide integrated 4-way deflection of catheter.	Similar to predicate device. Both devices use pull-lines to deflect the catheter tip. NuVision ICE Catheter allows independent rotation of the catheter tip..
Temperature Sensor	Incorporates a thermistor within the probe tip. The ultrasound system reads the thermistor and adjusts power to assure the probe never reaches temperature limit of 43^{o} C.	Ultrasound system energy delivery was calibrated to assure probe never reaches temperature limit of 43^{o} C.	Similar to predicate device. NuVision ICE Catheter allows use of real-time probe temperature feedback to make energy adjustments.

Testing completed:

The NuVision ICE Catheter was developed per the Guidance for Industry and FDA Staff, Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (2019). Non-clinical data includes bench-top performance evaluations, packaging validation, biological safety, electromagnetic compatibility, and acoustic output testing. The devices used for testing were manufactured in accordance with the design specifications and approved manufacturing documentation.

Dimensional and Performance

The catheter dimensional characteristics were evaluated to verify conformance to design specifications and EN ISO 10555-1:2013: Sterile, single-use intravascular catheters — Part 1: General requirements. The physical integrity, functionality, and overall performance of the catheter were evaluated including:

a) Visual and Dimensional Characteristics

b) Simulated Use
- Package opening and transfer to sterile field
- Sterile sleeve loading

c) Catheter Functional Performance
- Reach
- Deflection
- Rotation
- Radiopacity

d) Electro-Acoustic Performance

e) Durability
- Multiple insertions
- Rotation Cycling
- Deflection Cycling
- Tip Kinking and buckling
- Leakage
- Particulate generation
- Tensile strength

Sterilization and Shelf Life

The NuVision ICE Catheter is sterilized via Ethylene Oxide gas using a cycle validated per ISO 11135-1:2014 to a Sterility Assurance Level (SAL) of 10^{-6}. Product samples were subjected to sterilization processing, distribution conditioning, and aging and then tested for compliance to the product specification. Packaging performance was evaluated to demonstrate that the packaging system preserves its integrity and that of the device through the lifecycle of the product in accordance with ISO 11607-1 and ISO 11607-2 and its applicable referenced standards.

Biocompatibility

The NuVision ICE Catheter is made from materials that are used in commercially available medical devices, and commonly used in intravascular devices. The sterilized catheter was evaluated for biocompatibility in accordance with the EN ISO 10993 series standards.

Electromagnetic Compatibility and Electrical Safety

Acoustic Output was evaluated in accordance with FDA Guidance, Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (June 2019) and EN 60601-2-37:2008: Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2015).

Electrical and thermal safety testing was conducted in accordance with EN 60601-1:2006/ IEC 60601-1:2005/A1:2012: Medical electrical equipment — Part 1: General requirements for basic safety and essential performance and IEC 60601-2-37 Edition 2.1 2015: Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

Electromagnetic compatibility testing was evaluated, demonstrating compliance to IEC 60601-1-2 (4th Edition).

Conclusion:

The NuVision ICE Catheter and the predicate device have nearly identical intended use and very similar principles of operational and technological characteristics. The subject device and predicate device are both 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 tests, laboratory tests, electrical safety tests, and animal tests, it can be concluded that the NuVision ICE Catheter is safe and effective for the intended use, is as safe and effective as the predicate device, and is substantially equivalent to the cited predicate device.