



Food and Drug Administration
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May 10, 2016

Innovative Health, LLC.
Rafal Chudzik
Director of Engineering
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K160303

Trade/Device Name: Reprocessed Polaris X Steerable Diagnostic EP Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: April 8, 2016
Received: April 11, 2016

Dear Rafal Chudzik:

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.

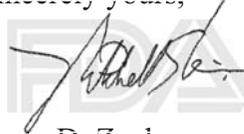
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<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 faint, light-colored 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

The item numbers included in the scope of K160303 are as follows:

Description	Item Number	Number of Electrodes	Electrode Spacing	French Size	Curve Type	Catheter Length
Polaris X Steerable Diagnostic EP Catheter	7000D	10	2.5 mm	6 F	270° Standard Curve	105 cm
	7001D	10	5 mm	6 F	270° Standard Curve	105 cm
	7003D	10	2.5/5/2.5 mm	6 F	270° Standard Curve	105 cm
	7004D	10	2/8/2 mm	6 F	270° Standard Curve	105 cm
	7005D	10	2/10/2 mm	6 F	270° Standard Curve	105 cm

Indications for Use

510(k) Number (if known)

K160303

Device Name

Reprocessed Polaris X Steerable Diagnostic Electrophysiology (EP) Catheter

Indications for Use (Describe)

The Reprocessed Polaris X Steerable Diagnostic EP Catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

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.

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SECTION 5: 510(k) SUMMARY

As required by 21 CFR 807.92(c)

Submitter's Name and Address:

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257

Contact Name and Information:

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Date prepared:

February 3, 2016

Device Information:

Trade/Proprietary Name: Reprocessed Polaris X Steerable Diagnostic
Electrophysiology Catheters
Common Name: Diagnostic Electrophysiology Catheter
Classification Name: Catheter, Recording, Electrode, Reprocessed
Classification Number: Class II, 21 CFR 870.1220
Product Code: NLH

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K003452	Polaris X Catheters	EP Technologies, Inc.
K924163	Explorer/360-Polaris-L.E./Jackman /Coron Sinus Electrophysiology	Boston Scientific, Corp.

Reference Device:

510(k) Number	510(k) Title	Reprocessor
K052414	Reprocessed Electrophysiology Catheter	Alliance Medical Corp.

Device Description:

The Reprocessed Polaris X Steerable Diagnostic EP Catheters are designed for use in intracardiac pacing and recording only. The catheters have been designed to carry electrical signals for the purpose of endocardial stimulation (pacing) or recording. The catheter is a uni-directional steerable catheter. The curve is actuated by means of a patented thumb-slide.

Indications for Use:

The Reprocessed Polaris X Steerable Diagnostic EP Catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

Technological Characteristics:

The purpose, design, materials, function, and intended use of the Reprocessed Polaris X Steerable Diagnostic Electrophysiology (EP) Catheters are identical to the predicate devices. There are no changes to the claims, clinical applications, patient population, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of these devices includes removal of visible soil and decontamination. Each device is inspected and function tested prior to packaging and labeling.

Functional and Safety Testing:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Polaris X Steerable Diagnostic EP Catheter. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional Testing
 - Visual Inspection
 - Dimensional Verification
 - Electrical Continuity and Resistance
 - Simulated Use
 - Mechanical Characteristics
- Electrical Safety Testing
 - Dielectric and Current Leakage
- Packaging Validation

The Reprocessed Polaris X Steerable Diagnostic EP Catheters are reprocessed no more than one (1) time. Each device is marked and tracked. After the device has reached the maximum number of reprocessing cycles, the device is rejected from further reprocessing. Reprocessing is performed only by Innovative Health. Innovative Health restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:

Innovative Health concludes that the Reprocessed Polaris X Steerable Diagnostic EP Catheters are as safe and effective as the predicate devices described herein.