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

September 30, 2016

Innovative Health, LLC
Rafal Chudzik
VP, R&D and Operations
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K161464
Trade/Device Name: Reprocessed Dynamic Tip Steerable Diagnostic Electrophysiology Catheters (Models per Table 1 in Enclosure)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: August 26, 2016
Received: August 29, 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.

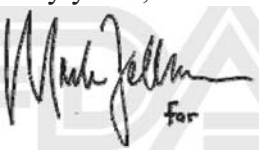
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

**Table 1: Reprocessed Single-Use Devices Included in K161464 Clearance**

| Item Number | Description | Electrodes | Spacing (mm) | Curve | French Size | Usable Length (cm) |
|---|---|---|---|---|---|---|
| 200131 | Dynamic Tip Steerable Diagnostic EP Catheter | 4 | 10 | Large 4.0 | 6 | 110 |
| 200344 | Dynamic Tip Steerable Diagnostic EP Catheter | 4 | 5 | Large 4.0 | 6 | 110 |
| 6DYNTP002 | Dynamic Tip Steerable Diagnostic EP Catheter | 4 | 2-5-2 | Large 4.0 | 6 | 110 |
| 6DYNTP006 | Dynamic Tip Steerable Diagnostic EP Catheter | 8 | 2 | Large 4.0 | 6 | 110 |
| 6DYNTP001 | Dynamic Tip Steerable Diagnostic EP Catheter | 10 | 2-5-2 | Large 4.0 | 6 | 110 |

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# Indications for Use

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

510(k) Number *(if known)*
K161464

Device Name
Reprocessed Dynamic Tip Steerable Diagnostic Electrophysiology Catheter

Indications for Use *(Describe)*
The Reprocessed Dynamic Tip Steerable Diagnostic Electrophysiology Catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

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.***

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*"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."*

## 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:**
Rafal Chudzik
VP, R&D and Operations
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**Date prepared:**
May 25, 2016

**Device Information:**

| | |
|---|---|
| *Trade/Proprietary Name:* | Reprocessed Dynamic Tip 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 |
|---|---|---|
| K891908 | Bard Tip Deflecting Electrode Catheter | C.R. Bard, Inc. |

**Device Description:**

The Reprocessed Dynamic Tip Steerable Diagnostic Electrophysiology (EP) Catheters are radiopaque, flexible, insulated catheters with a polymer shaft. The catheters have a plunger mechanism, which, when moved forward or back, results in curvature of the distal tip.

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

| Description | Item Number | Number of Electrodes | French Size | Electrode Spacing (mm) | Curve | Length (cm) |
|---|---|---|---|---|---|---|
| Dynamic Tip Steerable Diagnostic EP Catheter | 200131 | 4 | 6 | 10 | Large 4.0 | 110 |
| | 200344 | 4 | 6 | 5 | Large 4.0 | 110 |
| | 6DYNTP002 | 4 | 6 | 2,5,2 | Large 4.0 | 110 |
| | 6DYNTP006 | 8 | 6 | 2 | Large 4.0 | 110 |
| | 6DYNTP001 | 10 | 6 | 2,5,2 | Large 4.0 | 110 |

Table 5.1: Device Scope

**Indications for Use:**

The Reprocessed Dynamic Tip Steerable Diagnostic EP Catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

**Technological Characteristics:**

The purpose, design, materials, function, and intended use of the Reprocessed Dynamic Tip 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 Dynamic Tip 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 Dynamic Tip 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 Dynamic Tip Steerable Diagnostic EP Catheters are as safe and effective as the predicate devices described herein.