May 4, 2021

Innovative Health, LLC
Christina Fleming
VP, Compliance and Regulatory Affairs
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K203655
Trade/Device Name: Reprocessed Webster CS Bi-Directional 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: March 5, 2021
Received: March 8, 2021

Dear Christina Fleming:

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,

Aneesh Deoras
Acting Assistant 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

SECTION 10: DEVICE DESCRIPTION

Details of Reprocessed Devices:

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

Item Number	Description	Sheath Usable Length (cm)	French Size	Curve	Spacing (mm)
BD710DF282RTS	Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter	115	7F	D-F	2-8-2
BD710FJ282RTS	Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter	115	7F	F-J	2-8-2
BD710DF282CT	Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter with Auto ID	115	7F	D-F	2-8-2
BD710FJ282CT	Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter with Auto ID	115	7F	F-J	2-8-2

Table 10.1: Device Scope

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203655

Device Name
Reprocessed Webster CS Bi-directional Diagnostic Electrophysiology (EP) Catheters

Indications for Use *(Describe)*
The Reprocessed Webster CS Bi-directional Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures, i.e. stimulation and recording only. The catheter is designed for use in the coronary sinus.

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:
Christina Fleming
VP, Compliance and Regulatory Affairs
Innovative Health, LLC.
(480) 525-5972 (office)
(888) 965-7706 (fax)
tfleming@innovative-health.com

Date prepared:
December 14, 2020

Device Information:

Trade/Proprietary Name:	Reprocessed Webster CS Bi-directional 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
K170922	Reprocessed Webster CS Bi-Directional Diagnostic Electrophysiology Catheter	Innovative Health, LLC.
K101345	Webster CS Catheter with EZ Steer Technology, Webster CS Catheter with EZ Steer Technology and Auto ID	Biosense Webster

Device Description:
The Reprocessed Webster Coronary Sinus (CS) Diagnostic Electrophysiology (EP) Catheter is a steerable, multi-electrode catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart. The device is a 7FR catheter with a usable length of 115cm. The catheter has a high-torque shaft with a bi-directional deflectable tip section containing an array of platinum electrodes that can be used for stimulation and recording.

Standard features of this catheter include a braided bi-directional deflectable tip section with an array of platinum electrodes that includes a 2mm tip dome. Additionally, two asymmetric curve types are available providing two 180^0 opposed, single plane curves. The curve types include DF and FJ. A Rocker Lever is used to deflect the tip. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

For Devices with Auto ID Technology:
The catheter is equipped with Electronically Erasable Programmable Read Only Memory (EEPROM) which is used to store unique catheter identification information. CARTO EP Navigation Systems equipped with Auto ID Technology can access the stored information and automatically recognize he catheter information.

The catheter interfaces with CARTO EP Navigation Systems equipped with Auto ID Technology via interface cables with the appropriate connectors.

Note: Only the catheter is the subject of this submission. Any other related equipment is not included in the scope of this submission.

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

Item Number	Description	Sheath Usable Length (cm)	French Size	Curve	Spacing (mm)
BD710DF282RTS	Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter	115	7F	D-F	2-8-2
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BD710DF282CT	Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter with Auto ID	115	7F	D-F	2-8-2
BD710FJ282CT	Reprocessed Webster CS Bi-Directional Diagnostic EP Catheter with Auto ID	115	7F	F-J	2-8-2

Table 5.1: Item Numbers

This 510(k) adds two (2) reprocessing cycles to the same device cleared under K170922 and minor changes to the reprocessing and sterilization release method.

Indications for Use:
The Reprocessed Webster CS Bi-directional Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures, i.e. stimulation and recording only. The catheter is designed for use in the coronary sinus.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Webster CS Bi-directional Diagnostic 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 Webster CS Bi-directional Diagnostic EP Catheters.

This included the following:

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

The Reprocessed Webster Coronary Sinus (CS) Bi-directional Diagnostic Electrophysiology (EP) Catheters are reprocessed no more than three (3) times. 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.

Predicate Comparison:
A comparison of the device and reprocessing methods with the predicates are provided in the table below:

	This 510(k)	K170922	K101345
Device:	Identical	Identical	Identical
Reprocessing Cycles:	3	1	0
Reprocessing Method:	Change to processing parameters. Packaging configuration and label change. Shelf life change.	Cleared/validated process	N/A
Sterilization:	Change to release method. No change to the sterilization method or SAL.	Cleared/validated process	N/A
Routine Monitoring:	Change to frequency and adjustment of limits.	Cleared process	N/A

Table 5.2: Predicate Comparison

Conclusion:
Innovative Health concludes that the Reprocessed Webster Coronary Sinus (CS) Bi-directional Diagnostic Electrophysiology (EP) Catheters are substantially equivalent to the predicate devices described herein.