April 23, 2019

Innovative Health, LLC
Amanda Babcock
Principal Regulatory Affairs Specialist
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K182386
Trade/Device Name: Reprocessed Supreme Diagnostic Electrophysiology Catheters
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: March 15, 2019
Received: March 18, 2019

Dear Amanda Babcock:

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.

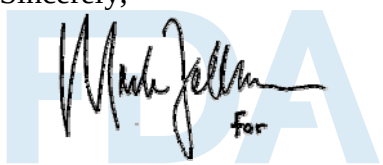
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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 this submission (K182386):

Description	Item Number	French Size	Electrode Spacing (mm)	Curve Type	Usable Length (cm)	Number of Electrodes
Supreme Fixed Diagnostic EP Catheter	401978	6	2-2-2	CSL	65	20
	402033	6	2-2-2-2-2-2-2-2-2-45-2-2-2-2-2-2-2-2-2-2	CSL	120	20
	402020	6	2-5-2-5-2-5-2-5-2-60-2-10-2-10-2-10-2-10-2	CRD	120	20
	401956	6	10	CRD	120	2
	402010	6	2-5-2	CRD-2	120	6
	402011	6	5-5-5	CRD-2	120	6
	401876	6	5-5-5-175-175	CRD-1	120	6
	401877	6	5-5-5-175-175	JSN	120	6
	401434	6	10	CRD	120	4
	401436	6	10	JSN	120	4
	401438	6	10	DAO	120	4
	401442	6	5	CRD	120	4
	401474	6	5	CRD-1	120	4
	402004	6	5	CRD-2	120	4
	401430	6	5	JSN	120	4
	401475	6	5	JSN-1	120	4
	401445	6	5	DAO	120	4
	401449	6	2-5-2	CRD	120	4
	401451	6	2-5-2	JSN	120	4
	401453	6	2-5-2	DAO	120	4
	401950	6	5	CRD	120	4
	401951	6	5	JSN	120	4
	401952	6	10	CRD	120	4