March 10, 2022

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

Re: K212165
Trade/Device Name: Reprocessed Carto Vizigo 8.5F Bi-Directional Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: PNE
Dated: March 7, 2022
Received: March 8, 2022

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 and Part 809); 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
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

The item number included in the scope of this submission is as follows:

Product Description	Item Number	Curve size	Outer Diameter	Usable length	Inner Diameter	Number of Electrode
Reprocessed Carto Vizigo Bi-Directional Guiding Sheath	D138501	Small (17 mm)	11.5F	71 cm	8.5F	4
	D138502	Medium (22 mm)	11.5F	71 cm	8.5F	4
	D138503	Large (50 mm)	11.5F	71 cm	8.5F	4

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)*
K212165

Device Name
Reprocessed Carto Vizigo 8.5F Bi-Directional Guiding Sheath

Indications for Use *(Describe)*
The Reprocessed Carto Vizigo Bi-Directional Guiding Sheath is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

The sheath curve can be visualized when used with compatible Carto 3 EP Navigation Systems.

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."

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:
Amanda Babcock
Regulatory Affairs Manager
Innovative Health, LLC.
(480) 525-5911 (office)
(888) 965-7705 (fax)
ababcock@innovative-health.com

Date prepared:
July 09, 2021

Device Information:

Trade/Proprietary Name:	Reprocessed Carto Vizigo 8.5F Bi-Directional Guiding Sheath
Common or Usual Name:	Guiding Sheath
Classification Name:	Reprocessed Catheter Introducer
Classification Number:	Class II, 21 CFR 870.1340
Product Code:	PNE

Predicate Device:

510(k) Number	Device	Manufacturer
K170997	Carto Vizigo Bi-Directional Guiding Sheath	Biosense Webster

Reference Device:

510(k) Number	Device	Manufacturer
K170311	Reprocessed Agilis NxT Steerable Introducer	Innovative Health, LLC.

Device Description:
The Reprocessed Carto Vizigo Bi-Directional Guiding Sheath is designed to provide accessibility and maneuverability in the cardiac anatomy. The steerable sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, and fluid infusion. A handle equipped with a rotating collar to deflect the tip clockwise ≤ 180° and counterclockwise ≤ 180°. The steerable sheath features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to allow fluoroscopic visualization.

Note: Only the steerable sheath and dilator are subject of this submission. The guidewire is purchased off-the shelf (K935170) and packaged with the reprocessed devices.

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

Product Description	Item Number	Curve size	Outer Diameter	Usable length	Inner Diameter	Number of Electrode
Reprocessed Carto Vizigo Bi-Directional Guiding Sheath	D138501	Small (17 mm)	11.5F	71 cm	8.5F	4
	D138502	Medium (22 mm)	11.5F	71 cm	8.5F	4
	D138503	Large (50 mm)	11.5F	71 cm	8.5F	4

Table 5.1: Device Scope

Indications for Use:
The Reprocessed Carto Vizigo Bi-Directional Guiding Sheath is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

The sheath curve can be visualized when used with compatible Carto 3 EP Navigation Systems.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed device is identical to the predicate device. There are no changes to the claims, clinical applications, patient populations, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of the reprocessed device 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 Carto Vizigo Bi-Directional Guiding Sheath. This included the following:

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

The device is reprocessed no more than one (1) time. Each device is marked, serialized 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 Carto Vizigo Bi-Directional Guiding Sheath is substantially equivalent to the predicate devices described herein.