June 3, 2020

Abbott
Winnie Yik
Senior Regulatory Affairs Specialist
15900 Valley View Court
Sylmar, California 91342

Re: K200721
Trade/Device Name: Agilis HisPro Steerable Catheter With Electrodes
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY, DRA
Dated: March 17, 2020
Received: March 19, 2020

Dear Winnie Yik:

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,

Hetal Odobasic
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200721

Device Name
Agilis HisPro Steerable Catheter With Electrodes

Indications for Use *(Describe)*

The Agilis HisPro Steerable Catheter With Electrodes is indicated to provide a pathway for delivery and support of transvenous devices within the chambers and vasculature of the heart and can be used for electrogram recording and stimulation.

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."

510(k) SUMMARY

Date Prepared:	June 2, 2020
Submitter:	Abbott (formerly St. Jude Medical), Cardiac Rhythm Management Division
Address:	15900 Valley View Ct. Sylmar, CA 91342 USA
Phone:	(818) 362-6822
Contact Person:	Winnie Yik Sr. Regulatory Affairs Specialist (818) 493-2077 wingyan.yik@abbott.com
Trade Name/Proprietary:	Agilis HisPro™ Steerable Catheter With Electrodes
Common Name:	Catheter, Steerable catheter
Model Number:	DS3H010-38
Product Code:	DQY, DRA
Classification:	Class II – 21 CFR 870.1250 Percutaneous catheter
Indications for Use:	The Agilis HisPro™ Steerable Catheter With Electrodes is indicated to provide a pathway for delivery and support of transvenous devices within the chambers and vasculature of the heart and can be used for electrogram recording and stimulation.
Device Description:	The Agilis HisPro Steerable Catheter With Electrodes is a deflectable, slittable catheter with two distal tip electrodes. It serves as a delivery conduit for devices such as cardiac leads. The distal portion can be formed into a "U" shape, when fully deflected, to facilitate positioning of the tip at a desired location in the heart. The 10.5 Fr catheter has a braided shaft with a multi-durometer outer Pebax jacket. The catheter has a 7 Fr diameter lumen that allows for delivery of a 6Fr cardiovascular transvenous device, including a 6Fr pacing lead.

510(k) SUMMARY

The Agilis HisPro catheter's proximal handle consists of a rotating actuator with passive locking mechanism for deflecting the distal portion, a hemostasis valve for leak-proof delivery, and an integrated cable incorporating a 4-pin electrical connection for connecting to external electrical systems via a commercially available electrophysiology cable. The tip electrodes provide the ability to sense intracardiac electrogram (EGM) and pace when connected to the Merlin™ Pacing System Analyzer (PSA) or the WorkMate Claris™ Recording System. The sensing and pacing feature of the Agilis HisPro catheter provides the ability to identify the desired location in the heart.

Accessories packaged for use with the Agilis HisPro catheter include dilator, guidewire for vascular access, cable adaptor pins for connection to the Merlin PSA via the electrophysiology cable, valve bypass tools for lead insertion, three-way stopcock and slitter. The catheter and the packaged accessories are provided as a sterile single-use device.

Predicate Devices:

Primary: Medtronic SelectSite™ Model C304
510(k) Number: K033989
This predicate has not been subject to a design-related recall.

Secondary: Abbott CPS Luminary Bideflectable Catheter
510(k) Number: K052575
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

Comparison to Predicate Devices:

The Agilis HisPro and the two predicate devices are all intended to serve as a conduit to allow delivery of transvenous devices to the heart. The Agilis HisPro Indications for Use is a combination of the primary predicate, Medtronic SelectSite C304 and secondary predicate, Abbott CPS Luminary Bideflectable Catheter. The primary function of the catheter to deliver a transvenous device into the heart is the same as both predicate devices. The expanded use statement of "electrogram recording and stimulation" is based on the CPS Luminary predicate device feature of tip electrodes, that allows for intracardiac signal detection via connection to external recording systems. The differences in indications do not alter the intended use of the device therefore the subject device intended use can be considered substantially equivalent to the predicate devices.

510(k) SUMMARY

The Agilis HisPro and SelectSite C304 share similar design principles and many of the technological characteristics. Both devices are deflectable/steerable through rotating handle design that controls the distal curve to deflect uni-directionally. Like the SelectSite C304, the Agilis HisPro has radiopaque shaft and tips for visualization via fluoroscopy, and is designed with slittable hub and shaft for catheter removal following cardiac lead delivery. The Agilis HisPro also shares many key technological characteristics with the CPS Luminary predicate device. They are both designed with radiopaque shafts and tips, deflectable distal curves with rotating handles and integrated tip electrodes for intracardiac signal detection.

Some key differences exist between the Agilis HisPro and the two predicates devices. In comparison to the SelectSite, they differ in their tip design in which the Agilis HisPro incorporates dual tip electrodes enabling intracardiac stimulation and signal recording. In the case of the predicate SelectSite catheter, physicians utilize the delivered lead to sense and pace to evaluate sites for lead placement. The sensing/pacing feature of the Agilis HisPro gives physicians an option to enable localization of the intracardiac signals to evaluate pacing sites using the catheter to facilitate lead placement instead of the delivered lead. As mentioned above, the CPS Luminary predicate device shares a similar integrated tip electrode feature for intracardiac signal detection. Therefore, this electrode feature of the Agilis HisPro catheter does not introduce different questions of safety and effectiveness as compared to the predicate devices. When compared against the CPS Luminary, the key difference is that the Agilis HisPro is slittable while CPS Luminary is not; however, slittability is a common feature in transvenous catheter design. Therefore, this difference does not raise different questions of safety and effectiveness.

Substantial Equivalence And Summary of Studies:

The Agilis HisPro Steerable Catheter with Electrodes is substantially equivalent to the predicate devices based on comparisons of the intended use, device functionality and technological characteristics. The following performance testing was performed to demonstrate the device meets its design specification and is as safe and effective as the predicate devices.

Performance Bench Testing

- Design Verification
  - Physical and Dimensional Characteristics

510(k) SUMMARY

- Electrical Characteristics
- Functional Characteristics
- Connector/Lead/Slitter Compatibility

- Design Validation
  - Simulated-use Bench Testing
- Packaging and Shelf Life testing
  - Nominal T=0
  - Accelerated Aging 12-month
- Biocompatibility
  - Hemocompatibility
  - Cytotoxicity
  - Systemic Toxicity
  - Sensitization/Irritation
  - Particulate Matter
- Electromagnetic Compatibility and Electrical Safety

Animal Testing

- Safety evaluation in comparison to Medtronic SelectSite C304
- Sensing/Pacing performance via compatibility with PSA and WorkMate Claris

The resulting evidence obtained from the design verification and validation testing demonstrated that the subject device is as safe and effective as the predicate devices.

The safety and effectiveness of the Agilis HisPro Catheter to deliver leads to the His Bundle has not been evaluated by the FDA.