December 19, 2019

C.R. Bard, Incorporated
Elizabeth Delahunty
Regulatory Affairs Manager
Moyne Upper
Enniscorthy, Ireland

Re: K192313
Trade/Device Name: Halo One Thin-Walled Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 23, 2019
Received: August 26, 2019

Dear Elizabeth Delahunty:

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,

For

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: 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)*

K192313

Device Name
Halo One Thin-Walled Guiding Sheath

Indications for Use *(Describe)*

The Halo One Thin-Walled Guiding Sheath is indicated for use in peripheral arterial and venous procedures requiring percutaneous introduction of intravascular devices. The Halo One Thin-Walled Guiding Sheath is not indicated for use in the neurovasculature or the coronary vasculature.

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.

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510(k) Summary

K192313

Halo One Thin-Walled Guiding Sheath

21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

ClearStream Technologies Ltd.
Moyne Upper,
Enniscorthy,
Co. Wexford, Ireland.
Phone: +353 53 9237111
Fax: + 353 53 9237100
Contact Person: Elizabeth Delahunty, RA Manager

Date of Submission: August 23, 2019

Subject Device:

Name of Device: Halo One Thin-Walled Guiding Sheath
Common or Usual Name: Catheter Introducer
Classification Name: Introducer, Catheter
Regulatory Class: II (Product Code DYB)
Regulation Number: 21 CFR 870.1340

Predicate Device:

510(k) Number: K161183
Name of Device: Halo One Thin-Walled Guiding Sheath
Common or Usual Name: Catheter Introducer
Classification Name: Introducer, Catheter
Regulatory Class: II (Product Code DYB)
Regulation Number: 21 CFR 870.1340

Device Description:

The Halo One Thin-Walled Guiding Sheath is designed to perform as both a guiding sheath and an introducer sheath.

The Halo One Thin-Walled Guiding Sheath consists of a thin-walled (Up to 1F reduction in outer diameter compared to standard sheaths of equivalent French size) sheath made from braided single-lumen tubing, fitted with a female luer hub at the proximal end and a formed atraumatic distal tip. The thin-wall design reduces the thickness of the sheath wall to help facilitate intravascular access from access sites including but not limited to radial, femoral, popliteal, and pedal.

A detachable hemostasis valve, employing a crosscut silicone membrane and incorporating a side arm terminating in a 3-way stopcock, is connected to the sheath luer hub. The sheath is supplied with a compatible vessel dilator that snaps securely into the hemostasis valve hub. The sheath has a strain relief feature located at the luer hub and a radiopaque platinum-iridium marker located close to the distal tip.

The sheath is supplied in 4F, 5F and 6F compatible sizes and lengths of 90cm, 70cm, 45cm, 25cm and 10 cm.

A vessel dilator which is 0.035” guide wire compatible is provided with each sheath. The 4F and 5F 10cm sheaths will also be offered with a 0.018” guide wire compatible dilator.

All sheath configurations (lengths) are provided with a hydrophilic coating over the distal portion of the sheath to provide a lubricious surface to ease insertion. The shorter sheath configurations (25cm and 10cm) are also provided without this coating.

Indications for Use of Device:

The Halo One Thin-Walled Guiding Sheath is indicated for use in peripheral arterial and venous procedures requiring percutaneous introduction of intravascular devices. The Halo One Thin-Walled Guiding Sheath is NOT indicated for use in the neurovasculature or the coronary vasculature.

Technological Comparison to Predicate Devices:

The Halo One Thin-Walled Guiding Sheath (subject device) has the following similarities to the predicate device, the Halo One Thin-Walled Guiding Sheath (clearance to market via K161183 on June 03, 2016):

- Same intended use
- Same indications for use
- Same target population
- Same operating principle
- Same fundamental scientific technology
- Same sterility assurance level and method of sterilization

The Halo One Thin-Walled Guiding Sheath (subject device), incorporates the following differences:

- Design Differences:
  1. Changed sheath shaft the manufacturing process.
  2. Changed braiding design.
  3. Changed sheath tip design.
  4. Changed dilator tip design rollback (buckling) while providing a transition to the guidewire.

- Material Differences:
  1. Changed material composition in the introducer shaft construction to address the failure mode which the predicate material caused.
  2. Changed durometer of material to provide improved flexibility and kink resistance.

Performance Data:

To demonstrate substantial equivalence of the subject device, the Halo One Thin-Walled Guiding Sheath to the predicate device, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following in vitro tests were performed on the subject device:

- Visual Inspection (Outer Surface)
  - Dilator Outer Surface
  - Sheath Outer Surface
- Simulated Use
  - Packaging Removal
  - Haemostasis Valve Connection
  - Sheath Inner Surface/Dilator Compatibility
  - Dilator Flushability
  - Valve Flushability
  - Sheath Flushability
  - Guidewire Compatibility
  - Dilator Disengagement by Hand
  - Tape Adhesion
- Dimensional Testing
  - Sheath ID
  - Sheath Length
  - Marker Band to Tip Position

  - Sheath OD
  - Dilator OD
  - Dilator Extension Length
- Radiopacity
- Penetration Force of Dilator/Sheath
- Trackability of Dilator and Sheath
- Visual Inspection (Tip Rollback-Dilator & Sheath)
- Bend Radius/ Kink
- Valve Leak
- Sheath Leak
- Sheath and Dilator Tensile Forces
- Hub Torque/Stress Cracking
- Hub Stress Cracking (48 Hour Test)
- Packaging
  - Visual Inspection
  - Bubble Emission of Pouches
  - Visual Inspection of Sterile Barrier Packaging Heat Seals
  - Seal Strength Tensile Method
- Particulate Characterization
- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility
- Material Mediated Pyrogenicity

The biocompatibility of the Halo One Thin-Walled Guiding Sheath was evaluated based on ISO 10993-1. The device is classified as an Externally Communicating Devices, Circulating Blood, Limited Contact (<24 hrs). The results from these tests demonstrate that the technological characteristics and performance criteria of the Halo One Thin-Walled Guiding Sheath are substantially equivalent to the predicate device, and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusions:

The subject device, the Halo One Thin-Walled Guiding Sheath, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The clinical and non-clinical tests

demonstrate that the Halo One Thin-Walled Guiding Sheath is substantially equivalent to the predicate device, Halo One Thin-Walled Guiding Sheath.