September 23, 2021

ClearStream Technologies Ltd.
Annmarie Fitzgerald
Senior Regulatory Affairs Specialist
Moyne Upper
Enniscorthy, Co. Wexford
Ireland

Re: K212708
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 25, 2021
Received: August 26, 2021

Dear Annmarie Fitzgerald:

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,

Finn Donaldson
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212708

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 nor 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

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

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Contact Person: Annmarie Fitzgerald, Senior RA Specialist, Regulatory Affairs

Date of Submission: August 25, 2021

Subject Device:

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

Predicate Device:

510(k) Number:	K192313
Name of Device:	Halo One Thin-Walled Guiding Sheath
Common or Usual Name:	Catheter, Introducer
Classification:	Introducer, Catheter
Regulatory Class:	II (Product Code: DYB)
Regulation Number:	21 CFR 870.1340

Classification Panel: Cardiovascular

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 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, tibial 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 Halo One Thin-Walled Guiding sheath is supplied in 4F, 5F and 6F compatible sizes and lengths of 90cm, 70cm, 45cm, 25cm and 10 cm. The Halo One Thin-Walled Guiding Sheath 4F, 5F and 6F 25cm and 10cm sheaths will be offered with a 0.018” and 0.035” guide wire compatible dilator option.

The Halo One Thin-Walled Guiding Sheath is also offered as an access kit in 4F,5F and 6F 10cm and 25cm lengths incorporating access needle (21G x 4cm or 19G x 7cm option available) and access guidewire in both 0.018” (0.018” x 80cm or 0.018” x 50cm option available) and 0.035” (0.035” x 80cm or 0.035” x 50cm option available) configurations to the existing predicate device product range.

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 the coating.

Intended Use / Indications for Use:

Device Intended Use

The Halo One Thin-Walled Guiding Sheath is indicated for use in arterial and venous procedures requiring percutaneous introduction of intravascular devices.

Indications for Use

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 nor the coronary vasculature.

Technological Comparison to Predicate Device:

The Halo One Thin-Walled Guiding Sheath has the following similarities to the Predicate Device Halo One Thin-Walled Guiding Sheath (K192313, cleared December 19, 2019):

- Same intended use.
- Same indications for use
- Same target population/conditions of use
- Same operating principle/mechanism of action
- Same fundamental scientific technology
- Similar packaging materials and configurations
- Same sterility assurance level and method of sterilization

The Halo One Thin-Walled Guiding Sheath (subject device) includes the following additions to the product range in comparison to the predicate device Halo One Thin-Walled Guiding Sheath (K192313, cleared December 2019):

1. The addition of 6F compatible size and lengths of 90cm, 70cm and 45cm to the range. A vessel dilator which is 0.035” guidewire compatible is provided with each sheath.
2. The 4F and 5F 25cm sheaths and 6F 10cm and 25cm sheaths will also be offered with a 0.018” guidewire compatible dilator.
3. The Halo One Thin-Walled Guiding Sheath will be further enhanced by the addition of access kits in 4F,5F and 6F 10cm and 25cm lengths incorporating access needle (21G x 4cm or 19G x 7cm option available) and access guidewire in both 0.018” (0.018” x 80cm or 0.018” x 50cm option available) and 0.035” (0.035” x 80cm or 0.035” x 50cm option available) configurations to the existing predicate device product range.

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate device, both technical characteristics and performance criteria were evaluated. Using FDA Guidance documents on non-clinical testing of medical devices and internal Risk Assessment procedures, testing for the following characteristics and performance criteria were evaluated for the subject device:

- Visual Inspection of sheath, access guidewire and access needle
- Simulated use of sheath, access guidewire and access needle
- Dimensional Testing of Dilator / Sheath
- Compatibility Testing of sheath, access guidewire and access needle
- Penetration Force of Dilator / Sheath
- Trackability of Dilator and Sheath
- Trackability of device in sheath
- Visual Inspection (Tip-Rollback)
- Bend Radius / Kink
- Leak Testing
- Needle Ultrasound visibility
- Packaging Testing
    - Visual Inspection
    - Bubble Emission of Pouches
    - Visual Inspection of Sterile Barrier Packaging Heat Seal
    - Seal Strength Tensile Method

The biocompatibility of the Halo One Thin-Walled Guiding Sheath was evaluated based on ISO 10993-1. The device is classified as an externally communication device, circulating blood, limited contact (<24hrs). The results from these tests performed in accordance with standards and FDA guidance, demonstrate that the technical characteristics and performance criteria of the Halo One Thin-Walled Guiding Sheath is substantially equivalent to the predicate and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusion:

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 protocol 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.