DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 3, 2016

ClearStream Technologies Ltd.
c/o Mark Job
Responsibility Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K161183
Trade/Device Name:
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 20, 2016
Received: May 24, 2016

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161183

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Halo One™ Thin-Walled Guiding Sheath

510(k) Summary

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:

Applicant:	ClearStream Technologies Ltd. Moyne Upper, Enniscorthy, Co. Wexford, Ireland.
Phone:	+353 53 9237111
Fax:	+ 353 53 9237100
Contact:	Fiona Ní Mhulláin, Senior RA/QA Manager
Date	February 04, 2016

Subject Device Name:

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

Predicate Device:

- Cordis Brite Tip Catheter Sheath Introducer System: (K984500, cleared December 23, 1998)

Device Description:

The Halo One™ Thin-Walled Guiding Sheath is designed to perform as both a guiding sheath and introducer sheath. The Halo One™ Thin-Walled Guiding Sheath consists of a thin-walled (1F wall thickness) sheath made from braided single-lumen tubing, fitted with a female luer hub at the proximal end and has a formed atraumatic distal tip.

A supplied hemostasis valve, employing a crosscut silicone membrane and incorporating a side arm terminating in a 3-way stopcock, may be 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 vessel dilator is compatible with a 0.035" (0.89 mm) guidewire. The longer sheath configurations are provided with a hydrophilic coating over the distal portion of the sheath to provide a lubricious surface to ease insertion. The short sheath configuration is marketed with an appropriately sized guide wire for initial insertion of the device.

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 nor the coronary vasculature.

Comparison of Indications for Use to Predicate Device:

The indications for use statement for the Halo One™ Thin-Walled Guiding Sheath does not raise any new issues of safety and effectiveness based on the proposed indications for use statement as compared to the predicate device. Therefore, the subject device, the Halo One™ Thin-Walled Guiding Sheath, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Devices:

The Halo One™ Thin-Walled Guiding Sheath has the following similarities to the predicate device, the Cordis Brite Tip Catheter Sheath Introducer System (clearance to market via K984500 on December 23, 1998):

- 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, incorporates the following differences:

- Braided shaft
- Thinner wall
- Marker band
- Hydrophilic coating
- Detachable haemostatic valve
- Component materials

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)
- Mini Guidewire Compatibility
- Packaging
  - Visual Inspection
  - Dye Penetration
  - Visual Inspection of Sterile Barrier Packaging Heat Seals
  - Seal Strength Tensile Method
- 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 Halo One™ Thin-Walled Guiding Sheath is substantially equivalent to the legally marketed predicate device, Cordis Brite Tip Catheter Sheath Introducer System.