MAY 3 2013

Sleek® OTW PTA Catheters

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 summary of the information upon which substantial equivalence determination is based as follows:

1. 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:	20 March 2013

2. Subject Device:

Device Trade Name:	Sleek® OTW PTA Catheters
Common or Usual Name:	Percutaneous Catheter (21 CFR 870.1250, Product Code LIT)
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Device:

Device Trade Name:	Sleek® OTW Percutaneous Transluminal Angioplasty (PTA) Catheter
Cleared 510(K) Number:	K102035
Date of Cleared 510(K):	01-Dec-10

4. Summary of Change:

The only difference between the predicate device, the Sleek® OTW PTA Catheter, and the subject device, the Sleek® OTW PTA Catheter LE, were the addition of balloon lengths.

5. Device Description:

The subject device, the Sleek® OTW PTA Catheter LE, is a balloon dilation catheter for angioplasty. A double lumen coaxial shaft features an inflatable balloon at its distal end. The proximal end provides a double hub connector, whose first port allows the attachment of an inflation device which is used to inflate and deflate the balloon through the outer lumen. A second hub port allows the advance of a guidewire throughout the whole length of the catheter using the distally open inner lumen.

The outer shaft lumen and the balloon are made of Polyamide, enclosing the inner High Density Polyethylene (HDPE) / Plexar / PolyEther Block Amide shaft. A Polycarbonate hub is connected to the outer and inner shaft proximally together with a PolyEther Block Amide strain relief tube.

6. Indications for Use of Device:

The Sleek® OTW PTA Catheters are intended for balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the Sleek® OTW PTA Catheter LE, are equivalent to those of the predicate device (Sleek® OTW PTA Catheter, K102035), in terms of intended use, indications for use, materials, fundamental scientific technology, target population, operating principle, packaging, sterility assurance level, and method of sterilization.

8. Performance Data:

To demonstrate the substantial equivalence of the subject device, the Sleek® OTW PTA Catheter LE, to the predicate device, its technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following additional *in vitro* tests were performed:

- Balloon Working Length
- Marker Band Alignment
- Burst Strength (Rated Burst Pressure)
- Burst Mode
- Proximal Tensile

- Sheath Compatibility
- Reinsertion
- Inflation Time
- Deflation Time
- Fatigue
- Balloon Outer Diameter
- Compliance

The results from these tests demonstrate that the technological characteristics and performance criteria of the subject Sleek® OTW PTA Catheter LE is comparable to the predicate device.

9. Conclusions:

The Sleek® OTW PTA Catheter LE met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols, and/or customer inputs. The Sleek® OTW PTA Catheter LE is substantially equivalent to the legally marketed predicate device, the Sleek® OTW PTA Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 3, 2013

ClearStream Technologies, Ltd.
c/o Ms. Fiona Ní Mhullain
Senior RA/QA Manager
Moyne Upper
Enniscorthy
County Wexford, Ireland

Re: K130786
Trade/Device Name: Sleek OTW PTA Catheters Line Extension
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 3, 2013
Received: April 5, 2013

Dear Ms. Fiona Ní Mhullain:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number (if known): K130786

Device Name: Sleek® OTW Percutaneous Transluminal Angioplasty Catheter

Indications for Use: The Sleek® OTW PTA Catheters are intended for balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Prescription Use__X_____ AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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