510(k) Summary

MAR 16 2010

Applicant Information

Date Prepared: February 10th 2010
Submitter: ClearStream Technologies Ltd

Address: Moyne Upper, Enniscorthy, Co.Wexford, Ireland.

Establishment Registration No: 9616666

Contact Person: Fiona Ni Mhullain, RA Manager

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Device Information

Trade Name: LitePAC PTA Catheter
Common Name: RX PTA Catheter
Classification Name: Percutaneous Catheter
Classification: Class II, 21 CFR 870.1250
Product Code: DQY

Predicate Device:
ClearStream Technologies Ltd, proposes its **Sleek PTA Catheter** cleared through the following 510(k) number submission: **K072947,** as the predicate device for this submission.

Device Description:

The LitePAC PTA Catheter is a standard rapid exchange PTA catheter. The proximal end provides a mono luer hub connector which allows the

attachment of an inflation device used to inflate and deflate the balloon through the outer lumen.

The rapid exchange port is positioned at the transition area between the stiffer hypotube and the more flexible distal portion and facilitates single operator use for insertion into a 0.014" guidewire.

Intended Use:

Balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Comparison to Predicate Device:

The ClearStream Technologies LitePAC catheter (K100490) is substantially equivalent to the predicate device The Sleek PTA Catheter (K072947).

Test Data:

The safety and effectiveness of the ClearStream LitePAC Catheter has been demonstrated through data collected from non-clinical design verification and design validation tests and analyses.

ClearStream Technologies Ltd	Special 510(k)
	LitePAC

Brief Comparison Summary

To demonstrate substantial equivalence of the applicant LitePAC PTA catheter to the predicate devices, the technological characteristics and performance criterion were evaluated using *in vitro* testing performed as outlined below:

***In Vitro* Testing**

Using FDA guidance documents on non-clinical testing of medical devices the following in vitro tests were performed:

- Visual and functional testing
- Catheter body diameter
- Measurement of balloon working surface
- Inflation/deflation testing
- Pull back testing
- Balloon Compliance
- Average burst pressure
- Tensile testing of proximal bond

Testing was also performed in compliance with ISO 10555-1 and ISO 10555-4.

The results from the tests demonstrate that the technological characteristics and performance criteria of the LitePAC PTA catheter are comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusion

ClearStream Technologies Ltd believes that the data and information presented in this application, including *in vitro* testing and numerous device similarities support a determination of substantial equivalence, and therefore market clearance of the LitePAC PTA catheter through this 510(k) premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 16 2010

ClearStream Technologies, Ltd.
c/o Fiona Ni Mhullain, Regulatory Affairs Manager
Moyne Upper, Enniscorthy
County Wexford
Ireland

Re: K100490
Trade/Device Name: LitePAC PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT, DQY
Dated: January 16, 2010
Received: February 19, 2010

Dear Ms. 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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K100490_____

Device Name: LitePAC RX PTA Catheters

Indications for Use:

Balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kuhns

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100490