AUG 0 4 2010

510(k) SUMMARY

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.87, 21 CFR 807.92.

Submitter Information: ClearStream Technologies Ltd, Moyne Upper, Enniscorthy, Co Wexford, Ireland. Phone: 00 353 53 9237111 Fax: 00 353 53 9237100.

Date Summary Prepared: 16th July, 2010

Contact Person: Fiona Ní Mhullain

Device Name: Trade Name(s): ReeFlex over the wire Peripheral Transluminal Angioplasty (PTA) Catheters

Classification Name: Percutaneous Catheter

Classification Regulation: 21 CFR 870.1250

Panel: Cardiovascular

Product Code: LIT

Predicate Device Information:

Device Name: ReeKross

Manufacturer: ClearStream Technologies Ltd

Reference: K083596

Device Description:

The ReeFlex™ is a balloon dilation catheter for angioplasty. It consists of a stainless steel guidewire shaft that extends from the proximal hub to the distal tip of the catheter. This stainless steel shaft has a spiral cut positioned at its distal end. The spiral cut is laser cut. A heat shrinkable layer is used to seal the spiral cut and ensure that the contrast solution remains in the inflation lumen only and does not leak into the guidewire lumen. This bodybond material is fused onto the outside diameter of the stainless steel shaft. A copolymer inflation lumen extends from the proximal hub of the catheter to the proximal shoulder of the balloon. The lumen of the shaft is used for the purpose of inflating and deflating the balloon. This outer is thermally fused to the balloon's proximal shoulder.

The balloon material is a Nylon blend. Low profile radiopaque bands are used to locate the balloon under fluoroscopy. These bands are swaged onto the bodybond material sealing the spiral cut section of the guidewire lumen.

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:

This device is equivalent to the predicate device in intended use, design characteristics and general physical characteristics. The difference between the two products is contained within the inner shaft. The ReeFlex has a spiral cut stainless steel shaft 1030mm in length positioned at its distal end (910mm fixed pitch followed by 120mm variable pitch). A heat shrinkable polymer layer is used to seal the spiral cut and ensure that the contrast solution remains in the inflation lumen only and does not leak into the guidewire lumen. The predicate device (the ReeKross) also contains a spiral cut stainless steel shaft however the length of this cut differs. This stainless steel shaft has a 120mm-

length spiral cut positioned at its distal end and this is coverered by a polymer layer not a heatshrinkable material. The only other difference between the two devices is the size range. The ReeFlex comes in the range 3.0mm-5.0mm balloon diameter x 40mm-220mm balloon length on a shaft length of 110cm and the ReeKross comes in the range: 3.0mm-6.0mm balloon diameter x 40mm-220mm balloon length on a shaft length 75cm and 2.0mm-4.0mm balloon diameter x 40mm-220mm balloon length on a shaft length 110cm.

Testing and Conclusion:

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
- Inflation/deflation testing
- Introducer sheath withdrawal
- Balloon Compliance
- Leak and rated burst pressure testing (cycle)
- Average burst pressure

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

The ReeFlex product falls under the product family of the predicate device the ReeKross. The ReeKross device master record has previously been reviewed and approved by the FDA under 510(k) # K083596. The ReeFlex product uses the same QuadFlex balloon material, component materials and spiral cut technology as the existing ReeKross (0.035") product except for the inner sealing layer on the guidewire lumen. The ReeKross

product range was previously validated thus only product attributes affected by the guidewire lumen inner sealing layer change were addressed for the ReeFlex validation.

The results from the tests demonstrate that the technological characteristics and performance criteria of the ReeFlex 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.

VP 334, 359, 423 and 427 were reviewed under the ReeKross submission.

VP 462 and VP 563 were carried out on the ReeFlex and have been included in this submission.

The testing carried out for the ReeKross product are listed in the functional validation summary.

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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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ClearStream Technologies, Ltd.
c/o Ms. Fiona N. Mhullain, Ph.D
Regulatory Affairs Manager
Moyne Upper
Enniscourthy, County Wexford, Ireland

Re: K101361
Trade Name: ReeFlex OTW PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: July 23, 2010
Received: July 27, 2010

Dear Dr. 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 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): K101361

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Device Name: ReeFlex PTA Catheter

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101361