OCT 12 2011

510(K) SUMMARY

Rev 01

Proprietary Name:	Bantam OTW PTA Catheter
Common Name:	OTW PTA Catheter
Classification Name:	Percutaneous Catheter (per 21 CFR 870.1250)
Device Classification:	Class II
Product Classification and Code:	DQY/LIT
Classification Panel:	Cardiovascular
Establishment Registration Number:	*9616666*
Contact Person:	Fiona Ni Mhullain Regulatory Affairs Manager Clearstream Technologies Ltd. Moyne Upper Enniscorthy, Co.Wexford Telephone: 00353 53 9237111 Facsimile: 00353 53 9237100 E-mail: fnimhullain@clearstream.ie

Performance Standards

Performance testing was carried out in compliance with ISO 10555-1 (# 6-6161).

Device Description

The Bantam (280mm balloon lengths) catheter is a standard over-the-wire PTA catheter. The co-axial catheter has a balloon located near the distal tip. One lumen is used for inflation of the balloon, while the internal lumen allows access to the distal tip of the catheter for guidewire insertion (max 0.018"). The balloon expands to a known diameter at specific pressure.

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.

Substantially Equivalent Devices

The following devices are substantially equivalent predicate devices:

- Bantam K093139

Comparison to predicate device

The predicate device is the same as the Bantam (280mm balloon lengths) in material composition, design, intended use and functionality. The Bantam (280mm balloon lengths) includes the addition of longer balloon lengths to the product range. A dimensionally differing outer will also be included to facilitate these longer balloons.

Brief Comparison Summary

To demonstrate substantial equivalence of the applicant Bantam (280mm balloon lengths) to the predicate devices, technological characteristics and performance criterion were evaluated using *in vitro* testing as indicated below:

***In Vitro* Testing**

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

- Visual and functional testing

- Catheter Body Diameters
- Inflation/Deflation time
- Introducer sheath withdrawal
- Leak and rated burst pressure testing
- Guidewire lumen stability test
- Tensile testing – Hub bond
- Tensile testing – proximal bond
- Working surface
- Balloon compliance
- Average burst

The results from these tests demonstrate that the technological characteristics and performance criteria of the Bantam (280mm balloon lengths) OTW PTA Catheter are comparable to the predicate device and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusion (Statement of Equivalence)

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 Bantam (280mm length balloon) OTW 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 –WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2011

Clearstream Technologies Ltd.
c/o Ms. Tina Lochner
4377 County Line Road
Chalfont, PA 18914

Re: K112335
Trade/Device Name: Bantam OTW PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY, LIT
Dated: October 3, 2011
Received: October 5, 2011

Dear Ms. Lochner:

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): K112335

Device Name: Bantam OTW 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)

)ivision Sign-Off)
)ivision of Cardiovascular De...

)10(k) Number K112335