510(k) SUMMARY
This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information:
ClearStream Technologies
Moyne Upper, Enniscorthy,Co.
Wexford, Ireland

Date Summary Prepared: January 3, 2008

Contact Persons:
Ian P Gordon
Senior Vice President
Emergo Group, Inc.
1705 S Capital of Texas Hwy Suite 500
Austin TX 78746
Fax 512-327-9998

Device Name:
Trade Name(s): Savvy Long and Sleek 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: Submarine Plus Percutaneous Transluminal Angioplasty (PTA) Catheters
Manufacturer: Invatec Innovative Technologies
Reference: K042537

Device Description:
A family of semi-compliant coaxial design catheters in various sizes. Each catheter has a balloon mounted on its distal tip. A hub/"Y" connector consists of a through lumen, allowing the catheter to track over a guidewire, and a balloon port used to inflate the balloon. To locate the balloon under fluoroscopy platinum iridium bands are provided at the shoulders of the balloon for all sizes. The proximal end of the catheter is provided with a transparent hub which allows easy observation of air bubbles. The hub is designed to facilitate easy removal of air bubbles during the preparation of the balloon.

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.

Testing and Conclusions:
Performance testing and compliance with recognized standards have established substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Clearstream Technologies, Ltd.
c/o Mr. Ian Gordon
Emergo Group, Inc.
1705 S. Capital of Texas Hwy, Suite 500
Austin, TX 78746

Re: K072947
Trade/Device Name: Savvy Long and Sleek PTA Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: January 8, 2008
Received: January 10, 2008

Dear Mr. Gordon:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

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): K072947

Device Name: ClearStream Technologies 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. Vorhees

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072947