K083094

BRIVANT MEDICAL ENGINEERING

Streamer Polymer Guidewire 510(k)

510(k) Summary

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

(1) Submitter's Name / Contact Person: Brivant Limited,
Parkmore West Business Park
Galway,
Ireland

JUL - 7 2009

Contact Person: Tomas Furey,
Vice President Regulatory Affairs
Tel: +353 91 385037
Fax: +353 91 766598

(2) Summary Preparation Date: May 14, 2009

(3) Device Name and Classification:

Trade Name:	Biotronik Streamer Polymer Guidewire
Common Name:	Guidewire
Classification Name:	Catheter, Guidewire
Device Classification:	Class II, 21 CFR §870.1330

(4) Summary of Substantial Equivalence

Predicate devices: Brivant Guidewire (K060551) and Whisper EDS Guidewire (K030019)

The Streamer Polymer Guidewires have minor design differences from the predicate Brivant guidewire and Whisper EDS Guidewire.

The Streamer Polymer guide wires are intended for use in the coronary and peripheral vasculature to facilitate the selective placement of interventional catheters with compatible guidewire lumen and Biotronik coronary venous leads.
The intended use is similar to that of the Whisper EDS and the Brivant guidewire with features of the Streamer intended use incorporated into both predicates.

The techological characteristics of the Streamer Guidewire and the predicate guidewires are closely similar. Where there are differences these differences are minor such that they do not affect safety or effectiveness. Brivant have conducted testing which compares the techical similarities between the Streamer Guidewire and predicate devices and this data demonstrates that the minor technical differences have not diminished safety or effectiveness

As a result the Streamer Polymer Guidewire is substantially equivalent to the Brivant Guidewire predicate.

(5) Description of the Device:

The Biotronik Streamer polymer guide wire is a disposable medical device designed for single use only. It consists of a PTFE coated 195cm 0.014" diameter stainless steel core wire, one end of which is reduced in diameter over a 38cm segment in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product a reduced area of stiffness and is varied to produce 3 unique levels of support, standard support, extra support (ES) and extra distal support (XT). There are a total of 8 versions of the guidewire, 2 standard support versions (straight & J), 4 extra support versions (straight and J, Bulach and Berlin) and 2 extra distal support versions (straight & J).
The distal part of the reduced section is covered with a platinum tungsten spring coil of equivalent diameter to the main core body. This provides greater visibility on x-ray equipment. A 30cm length of blue heat shrink polymer tubing is applied over the tapered distal end of the wire and ground to form a constant outer diameter, OD. The polymer jacket over distal coils provides for smoother lead-guidewire interaction.

(6) Statement of Intended Use:

The Streamer Polymer guide wires are intended for use in the coronary and peripheral vasculature to facilitate the selective placement of interventional catheters with compatible guidewire lumen and Biotronik coronary venous leads.

(7) Technological Characteristics.

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are substantially equivalent to the currently marketed devices.

(8) Summary of Testing:

Performance testing involving the following testing has been completed; tensile strength, torque strength, torque response, coating performance, radiopacity, tip flexibility, catheter compatibility testing, accelerated aging, transportation testing, sterilisation validation adoption, and biocompatibility testing in compliance with ISO 10993-1 and ISO10993-4 has been successfully completed.

The successful tests demonstrated the Streamer Polymer Guidewires consistently performed within their design parameters, are safe and effective and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Brivant, Limited
% Mr. Tomas Furey
Vice President Regulatory Affairs
Parkmore West Business Park
Galway
IRELAND

JUL - 7 2009

Re: **K083094**
Trade/Device Name: Streamer Polymer Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: May 29, 2009
Received: June 2, 2009

Dear Mr. Furey:

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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Volkmer

for 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): K083094

Device Name: Streamer Polymer Guidewire

Indications for Use:
The Streamer Polymer guide wires are intended for use in the coronary and peripheral vasculature to facilitate the selective placement of interventional catheters with compatible guidewire lumen and Biotronik coronary venous leads.

Prescription Use__X__ (Per 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083094