# 510(k) Summary
## as required by 21 CFR 807.92(c)

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| **Device Name** | Cruiser-18 Guidewire | |
| **Submitters name/contact details** | Brivant Ltd,<br>Parkmore West Business Park,<br>Galway,<br>Ireland<br><br>Contact Details:<br>Tomas Furey<br>Operations Manager,<br>Tel: +353 91 385037<br>Fax: +353 91 766598 | SEP 3 2010 |
| **Summary Preparation Date** | 19th July 2010 | |
| **Device Name & Classification** | Trade Name: | Cruiser-18 Guidewire |
| | Common Name: | Guidewire |
| | Classification Name: | Catheter, Guidewire |
| | Device Classification: | Class II, 21 CFR §870.1330 |
| | Product Code: | DQX |
| **Intended Use** | Intended Use:<br>The Cruiser-18 Guidewires are intended for use in the peripheral vasculature.<br><br>Contraindications:<br>The Cruiser-18 guide wire is not intended for use in the coronary or cerebral vasculature.<br>Patients judged not acceptable for percutaneous intervention (PPCI) | |
| **Device Description** | The guide wire is a disposable medical device designed for single use only. It consists of a 0.018" diameter stainless steel core wire, one end of which is reduced in diameter over a 13cm segment in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product a reduced area of stiffness. This reduced section is covered with a spring coil of equivalent diameter to the main core body. The coiled segment consists of a stainless steel coil placed over a radiopaque coil made of a platinum tungsten alloy. This coil provides greater visibility on x-ray equipment. The profile of the reduced section is varied to provide a range of products with mixed stiffness. | |

| **Predicate Devices** | **Manufacturer** | **510k** | **Date** |
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| | Brivant Ltd, Brivant Guidewire | K060551 | 07 Jun 2006 |
| | Brivant Ltd, Courier Guidewire | K073082 | 09 Jan 2008 |

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| **Principle of Operation** | The Cruiser-18 Guidewire is operated manually by a manual process |
| **Comparison of** | The Cruiser-18 wire has minor differences in construction to the approved |



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| **Technological Characteristics** | Brivant Guidewire.<br>In vitro bench testing was performed to support a determination of substantial equivalence (i.e. tip flexibility, tip flexibility and device compatibility) between the Cruiser-18 Guidewires (in its various configurations) and the predicate devices.<br>The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs comparably to the predicate devices. The differences in construction between the Cruiser-18 wire and the predicate device raise no new issues of safety and effectiveness such that the Cruiser-18 Guidewire is considered substantially equivalent to the predicate devices. |
| **Performance Testing (non-clinical)** | In vitro bench tests were carried out to demonstrate equivalence with reference to the FDAs guidance document "Coronary and Cerebrovascular Guidewire Guidance, Jan 1995".<br>The following bench tests were performed:<br>- Tensile Strength<br>- Torque Strength<br>- Outer Diameter measurement<br>- Torque Response<br>- Catheter Compatibility<br>- Coating Adherence/Coating Integrity<br>- Tip Flexibility<br><br>The results from these performance evaluations demonstrated that the Cruiser-18 Guidewire met the acceptance criteria defined in the product specification and performed comparably to the predicate device. Biological Safety of the device has been established through biocompatibility testing carried out in compliance with ISO 10993-1 |
| **Conclusions** | Based on safety and performance testing, technological characteristics and the indications for use for the device, the Cruiser-18 Guidewire has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Brivant, Ltd.
c/o Tomas Furey, Operations Manager
Parkmore West Business Park
Galway, County Galway
Ireland

SEP 3 2010

Re: K102211
Trade/Device Name: Cruiser-18 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: July 20, 2010
Received: August 5, 2010

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. 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 Statement

SEP 3 2010

**510(k) Number (if known):** K102211

**Device Name:** **Cruiser-18 Guidewire**

**Indications for Use:** The Cruiser-18 Guidewires are intended for use in the peripheral vasculature

**Contraindications:** The Cruiser-18 guide wire is not intended for use in the coronary or cerebral vasculature.
Patients judged not acceptable for percutaneous intervention (PPCI)

Donna R. McNamara

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102211