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K061453

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510(K) SUMMARY

Submitter:	Guidant Corporation Cardiac Rhythm Management (CRM) 4100 Hamline Avenue North St. Paul, Minnesota 55112-5498
Contact:	Kathleen Vittum Regulatory Affairs Associate
Telephone:	(800) 227-3422 or direct (651) 582-4820
FAX:	(612) 582-5134
Email:	kathleen.vittum@guidant.com
Date of Summary:	May 23, 2006
Trade Name:	HI-TORQUE WHISPER VIEW™ Guide Wire, Model #4631-4639
Common Name:	Guide Wire
Classification Name:	Catheter Guide Wire, (21 CFR 870.1330, Product Code DQX)
Predicate	HI-TORQUE WHISPER™ Guide Wire, K030019

Device Description

The guide wire is comprised of a stainless steel tapered core with a flexible tip, jacketed by tungsten-loaded polyurethane on the distal portion and polytetrafluoroethylene (PTFE) on the proximal portion of the wire. The polyurethane is covered with a hydrophilic coating to increase lubricity. The guide wire is 190 cm long with a maximum outer diameter of 0.0145. The guide wires are available with either a straight distal tip that is shapeable, or a preformed 'J' distal tip shaped specifically for accessing the coronary sinus.

Intended Use

The HI-TORQUE® WHISPER VIEW™ Guide Wire is intended to aid in the placement of a Guidant implantable coronary venous lead in the coronary venous vasculature.

Technological Characteristics

The HI-TORQUE® WHISPER VIEW™ Guide Wire is identical to the predicate HI-TORQUE® Whisper Wire in all respects with the exception of two modifications – an

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increased tungsten load in the polyurethane coating and a change in the tempering method for the stainless steel wire core.

Performance data

The results of verification testing demonstrate that the HI-TORQUE® WHISPER VIEW™ Guide Wire meets established acceptance criteria and performs in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during testing.

Conclusion

The Guidant HI-TORQUE® WHISPER VIEW™ Guide Wire is similar to the predicate WHISPER Guide Wire with respect to intended use, materials, technological characteristics and performance properties, and uses sterilization processes identical to the predicate device. Testing did not identify any new safety or effectiveness concerns. Therefore the HI-TORQUE® WHISPER VIEW™ Guide Wire is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2006

Guidant Corporation
c/o Ms. Kathleen Vittum
Regulatory Affairs Associate
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: K061453
Trade Name: Hi-Torque Whisper View Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II (two)
Product Code: DQX
Dated: May 24, 2006
Received: May 25, 2006

Dear Ms. Kathleen Vittum:

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 Office of Compliance at (240) 276- 0120 (see bottom for #s). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Whisper View Special 510(k) Submission
Attachment 2

INDICATION FOR USE STATEMENT

510(k) Number (if known): K061453

Device Name: **HI-TORQUE WHISPER VIEW™ GUIDE WIRE**

Indications For Use: The HI-TORQUE WHISPER VIEW GUIDE WIRE is intended to aid in the placement of a Guidant implantable coronary venous lead in the coronary venous vasculature.

Prescription Use: [X] AND/OR Over-The-Counter Use: [ ]

(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K061453