MAY 1 4 2003

K030549

Appendix A – 510(k) Summary

Submitter	Guidant Corporation, Vascular Intervention
Submitter's Address	26351 Ynez Road Temecula, CA 92591
Telephone	(909) 914-4527
Fax	(909) 914-0339
Contact Person	Stacey Brown
Date Prepared	February 20, 2003
Device Trade Name	HI-TORQUE PILOT™ 50 Guide Wire with Hydrocoat Hydrophilic Coating HI-TORQUE PILOT™ 150 Guide Wire with Hydrocoat Hydrophilic Coating HI-TORQUE PILOT™ 200 Guide Wire with Hydrocoat Hydrophilic Coating
Device Common Name	Guide Wire
Device Classification Name	Guide Wire Catheter
Device Classification	Class II
Summary of substantial equivalence	The design, materials, method of delivery and intended use features of the HI-TORQUE PILOT™ Guide Wires with Hydrocoat Hydrophilic Coating are substantially equivalent with regard to these features in the predicate device, the HI-TORQUE WHISPER™ MS Guide Wire with Hydrocoat Hydrophilic Coating (K002206, August 24, 2000; K013092, December 13, 2001; and K020340, March 1, 2002).

K030549

Device description	The HI-TORQUE PILOT™ Guide Wire with Hydrocoat Hydrophilic Coating is a guide wire with a maximum diameter of 0.0140" and is available in 175 cm and 190cm extendable lengths and a 300 cm exchange length. There are three HI-TORQUE PILOT™ Guide Wire designs with varying tip stiffness (i.e., HI-TORQUE PILOT™ 50, HI-TORQUE PILOT™ 150, and HI-TORQUE PILOT™ 200 Guide Wires). The distal tip of the guide wire is available either as a straight tip that is shapeable, or as a pre-shaped "J". The straight shape allows the physician to shape the tip according to his/her preference; the J shapes provide the physician the convenience of a J shape without manual shaping. Brachial and femoral markers are located on the proximal segment of the 190 cm and 300 cm guide wires to indicate when the tip of the guide wire is about to exit the guide catheter. The proximal section of the wire is coated with polytetrafluroethylene (PTFE). The distal, polyurethane-covered area, of the wire is coated with hydrocoat hydrophilic coating.
Intended Use	To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) and compatible stent devices.
Technological characteristics	The HI-TORQUE PILOT™ Guide Wire incorporates the same fundamental scientific technology as the predicate device.
Performance data	The results of the verification testing demonstrate that the HI-TORQUE PILOT™ Guide Wires meet the established acceptance criteria and performs in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2003

Guidant Corporation
Ms. Stacey Brown
Regulatory Affairs Associate
26531 Ynez Road
Temecula, CA 92591-4628

Re: K030549
Trade/Device Name: HI-TORQUE PILOT™ Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 15, 2003
Received: April 16, 2003

Dear Ms. Brown:

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.

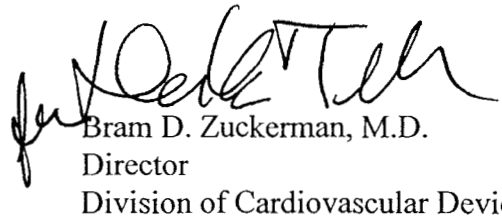
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Appendix B – Indications for Use Statement

510(k) number (if known)	K030549
Device name	HI-TORQUE PILOT™ 50 Guide Wire with Hydrocoat Hydrophilic Coating HI-TORQUE PILOT™ 150 Guide Wire with Hydrocoat Hydrophilic Coating HI-TORQUE PILOT™ 200 Guide Wire with Hydrocoat Hydrophilic Coating
Intended Use	To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) and compatible stent devices.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030549