MAY 02 2002

K021284

510(K) Summary

1. **Device Trade Name**
   EASYTRAK® Guiding Catheter

2. **Device Common Name**
   Guiding Catheter

3. **Device Description**
   The EASYTRAK Guiding Catheter is a catheter with a 0.087" inner diameter. The catheter is available in five shapes which include a Coronary Sinus-Multi Purpose Hook (CS-MPH), Coronary Sinus-Hook (CS-H), Coronary Sinus-Multi-Purpose Long (CS-MPL), and Coronary Sinus-Amplatz 6 (CS-A6). The catheter is available in working lengths ranging from 30cm to 47cm.

4. **Intended Use**
   The Guidant EASYTRAK Guiding Catheter is intended to access the coronary sinus. The Catheter may serve as a conduit for the delivery and support of devices introduced into the coronary venous system.

5. **Technological Characteristics**
   Comparisons of the EASYTRAK Guiding Catheter and predicate devices show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.

6. **Performance Data**
   In vitro bench testing and in vivo performance evaluations demonstrated that the EASYTRAK Guiding Catheter met the acceptance criteria and performed similarly to the predicate device (e.g., TOURGUIDE). An animal study was conducted and the results of the *in vivo* animal evaluation show that the EASYTRAK Guiding Catheter is acceptable. No new safety or effectiveness issues were raised during the testing program. The EASYTRAK Guiding Catheter may be considered substantially equivalent to the predicate device.

   The EASYTRAK Guiding Catheter was evaluated in a clinical investigation. The results demonstrated that the EASYTRAK Guiding Catheter is safe and effective.

7. **Conclusion**
   The Guidant EASYTRAK Guiding Catheter is substantially equivalent to the currently marketed Cardima VUEPORT™ Coronary Sinus Balloon Occlusion Guiding Catheter (K973298, cleared June 26, 1998) with regards to intended use, and to the Advanced Cardiovascular Systems (ACS) TOURGUIDE™ Guiding Catheter (K953987, cleared December 7, 1995) with regards to design characteristics and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2002

Ms. Karen S. Alsop
Pr. Regulatory Affairs Associate
Guidant Corporation
4100 Hamline Avenue N
St. Paul, MN 55112

Re: K021282
Trade Name: LV-1 Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold fitting
Regulatory Class: Class II (two)
Product Code: DTL

Re: K021283
Trade Name: Guidant Balloon Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO

Re: K021284
Trade Name: EASYTRAK® Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: DQY

Re: K021285
Trade Name: HI-TORQUE® Guide Wires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: April 17, 2002
Received: April 18, 2002

Dear Ms. Alsop:

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 enclosures) 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021284

Device Name: EASYTRAK® Guiding Catheter

Intended Use/Indications for Use:

The Guidant EASYTRAK Guiding Catheter is intended to access the coronary sinus. The catheter serves as a conduit for the delivery and support of devices introduced into the coronary venous system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021284

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

Prescription Use ✓
(Per 21 CFR 801.109)