AUG 0 2 2002

K021455

510(K) Summary

1. **Device Trade Name**
   6F RAPIDO™ Guiding Catheter
   8F RAPIDO™ Guiding Catheter

2. **Device Common Name**
   Percutaneous Catheter

3. **Device Description**
   The RAPIDO Guiding Catheters are available in two French sizes (6F and 8F). The 6F RAPIDO Guiding Catheter has a standard working length of 69 cm. The 8F RAPIDO Guiding Catheter has as standard working length of 47 cm.

4. **Intended Use**
   The Guidant Guiding Catheter is intended to access the coronary venous system, and may be used as a dual-catheter assembly. The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

5. **Technological Characteristics**
   Comparisons of the 6F/8F RAPIDO Guiding Catheters 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**
   Testing demonstrated that the 6F/8F RAPIDO Guiding Catheters met the acceptance criteria and performed similarly to the predicate device (EASYTRAK Guiding Catheter). No new safety or effectiveness issues were raised during the testing program. The 6F/8F RAPIDO Guiding Catheter may be considered substantially equivalent to the predicate device.

7. **Conclusion**
   The Guidant 6F/8F RAPIDO Guiding Catheters are substantially equivalent to the currently marketed EASYTRAK Guiding Catheter (K021284, May 2, 2002) with regards to intended use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2002

Guidant Corporation
c/o Ms. Karen S. Alsop
Principal Regulatory Affairs Associate
Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: K021455
Trade Name: RAPIDO™ Guiding Catheters, 6F and 8F
Regulation Number: 21 CFR.870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: May 3, 2002
Received: May 6, 2002

Dear Ms. Alsop:

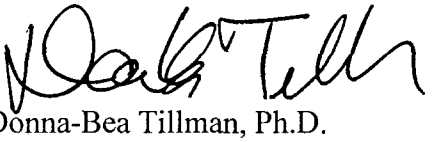
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: Guidant Corporation
4100 Hamline Avenue North
St. Paul, MN 55112

510(k) Number (if known): *To be assigned by FDA*

Device Names: RAPIDO™ Guiding Catheter, 6F and 8F

Intended Use/Indications for Use:

The Guidant Guiding Catheter is intended to access the coronary venous system, and may be used as a dual-catheter assembly. The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, 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)

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

Division of Cardiovascular & Respiratory Devices
510(k) Number K021455