K 031459

JUL 2 3 2003

510(K) Summary

1. **Device Trade Name**
   RAPIDO™ Cut-Away™ Cutter

2. **Device Common Name**
   Cutter

3. **Device Description**
   The Cutter is an accessory manufactured for use with the RAPIDO Cut-Away Guiding Catheter, for the treatment of Congestive Heart Failure. The Cutter attaches to the lead and cuts one wall of the guiding catheter as it is removed from the patient, allowing the guiding catheter to be removed from the lead. This new removal process is necessitated by the larger IS-1 terminal pin that future leads will incorporate. The Cutter currently has only one manufacturing configuration.

   The Cutter consists of three sections; A handle, a stainless steel blade and a lead management section. The lead management section stabilizes the lead, prior to, and during the cutting procedure. After the lead has been fixed in the patient, the cutter is connected to the lead body as close to the catheter hub as possible. Holding the cutter stationary and fixed to a surface, the doctor pulls the catheter against the cutter blade. The hub is cut first and then the catheter section.

4. **Intended Use**
   The RAPIDO Cut-Away Cutter is intended to assist with the removal of the RAPIDO Cut-Away Guiding Catheter that is used to access the coronary venous system. The cutter cuts the guiding catheter after lead implantation.

5. **Technological Characteristics**
   Comparisons of the RAPIDO Cut-Away Cutters and predicate devices show that the technological characteristics such as design and intended use are substantially equivalent to the currently marketed predicate device (Medtronic Attain Cutter).

6. **Performance Data**
   Testing demonstrated that the RAPIDO Cut-Away Cutters met the acceptance criteria and performed similarly to the predicate device . No new safety or effectiveness issues were raised during the testing program. The RAPIDO Cut-Away Cutter may be considered substantially equivalent to the predicate device.

7. **Conclusion**
   The Guidant RAPIDO Cut-Away Cutters are substantially equivalent to the currently marketed Medtronic Attain Cutters (K024035, cleared 12/30/02) 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

JUL 23 2003

Guidant Corporation
Cardiac Rhythm Management
c/o Mr. Shah Hilali
Senior Regulatory Affairs Associate
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: K031459
Trade Name: RAPIDO™ Cut-Away™ Cutter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: May 7, 2003
Received: May 8, 2003

Dear Mr. Hilali:

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. 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 (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

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* K031459

Device Names: RAPIDO™ Cut-Away™ Cutter

Intended Use/Indications for Use:

The RAPIDO™ Cut-Away™ Cutter is intended to facilitate RAPIDO™ Cut- Away™ Guiding Catheter removal after the Guidant coronary venous lead is positioned.

(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 Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031459