GUIDANT

FEB 1 3 2006

K052965

5. 510(K) SUMMARY

Owner:	Guidant Corporation Cardiac Rhythm Management (CRM) 4100 Hamline Avenue North St. Paul, Minnesota 55112-5798
Contact:	Linda Kleinsasser, RAC Senior Regulatory Affairs Associate Telephone: (800) 227-3422, x24106 or direct (651) 582-4106 Fax: (651) 582-5134 Email: linda.Kleinsasser@guidant.com
Date of Summary:	October 20, 2005
Common Name:	Stylet
Trade Name:	EASYTRAK® 2 Stylet
Classification Name:	Class II Per 21 CFR 870.1380, Catheter Stylet, Cardiovascular Panel
Predicate:	Stylet Accessory, Model 6602, K905674, cleared January 30, 1991 IRONMAN Guide Wire, Model 6725, K021285, cleared May 2, 2002

5.1. DEVICE DESCRIPTION

The EASYTRAK® 2 Stylet is designed for delivery of the EASYTRAK® 2 lead in the coronary veins. The stylets come in three lengths corresponding to the lengths of the EASYTRAK® 2 leads.

The EASYTRAK® 2 Stylet consists of a stainless steel wire with a polypropylene hub at the proximal end. The distal end of the wire has a stop-coil designed to prevent the stylet from exiting through the distal end of the lead.

5.2. INTENDED USE

The EASYTRAK® 2 Stylet is intended to aid in the placement of a Guidant EASYTRAK® 2 implantable venous lead in the coronary venous vasculature.

5.3. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Comparisons of the EASYTRAK® 2 Stylet and the predicate devices show that the technological characteristics such as Intended Use, material, packaging, shelf life and sterilization are substantially equivalent to the currently marketed predicate devices.

5.4. TESTING

Testing demonstrated that the EASYTRAK® 2 Stylet met the acceptance criteria. No new safety or effectiveness issues were raised during the testing program. The EASYTRAK® 2 Stylet may be considered substantially equivalent to the predicate devices.

5.5. CONCLUSION

The Guidant EASYTRAK® 2 Stylet are substantially equivalent to the currently marketed Stylet accessory, Model 6602 (K905674, cleared 1/30/1991) and the IRONMAN Guide Wire, Model 6725 (K021285, cleared 5/2/2002).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2006

Guidant Corporation
c/o Ms. Linda Kleinsasser, RAC
Senior Regulatory Affairs Associate
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: K052965
Trade Name: EASYTRAK® 2 Stylet
Regulation Number: 21 CFR 870.1380
Regulation Name: Catheter Stylet
Regulatory Class: II (two)
Product Code: DRB
Dated: January 9, 2006
Received: January 10, 2006

Dear Ms. Kleinsasser:

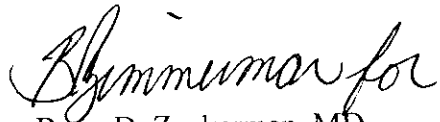
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

Enclosure

4. INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K052965

Device Name: Stylet

Indication for Use:

The EASYTRAK® 2 Stylet is intended to aid in the placement of a Guidant EASYTRAK® 2 implantable venous lead in the coronary venous vasculature.

Prescription Use ____X_____ OR Over-The-Counter _____

(Per 21 CFR 801.109)

(PLEASE DONOT 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 K052965