K052884

Remington Medical, Inc.

MAY 19 2005

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	Remington Medical Inc.
2.	*Address:*	6830 Meadowridge Court Alpharetta, Georgia 30005
3.	*Telephone:*	770-888-8520
4.	*Contact Person:*	Don Rosvold
5.	*Date Prepared:*	March 31, 2005
6.	*Registration Number:*	1056553

B. Device

1.	*Name:*	Guidant Model 6149 Pacing Vector Selector Patient Adapter Cable
2.	*Trade Name:*	Adapter Cable
3.	*Common Name:*	Adapter Cable
4.	*Classification Name:*	External Pulse Generator, Electrode Function Analyzer, and Generator Function Analyzer
5.	*Product Code:*	DTA, DTC, and DTE
6.	*Class:*	III
7.	*Regulation Number:*	870.3600, 870.3630, and 870.3720

C. Identification of Legally Marketed Devices

1.	*Name:*	ERA 300
2.	*K Number:*	K032613 and K964190
3.	*Date Cleared:*	December 8, 2003 and July 10, 1997

Remington Medical, Inc.

D. Description of the Device

The Model 6149 Pacing Vector Selector Cable Switch was designed to interface between the Guidant Model 3105 or 3106 Pacing System Analyzer and Guidant 6697 Patient Cables. It is manually operated and has no active circuits or power sources.

It is a 3-channel Patient Adapter Cable, easily switchable between PSA vector measurements on implanted leads without relocating alligator clips on the lead terminal.

A 2-pole, 5 position switch is integrated into the 3-channel molded connector housing on the distal end of the cable. The pacing vectors options provided are:

- Left Ventricle Tip to Right Ventricle Coil
- Left Ventricle Ring to Right Ventricle Coil
- Left Ventricle Ring to Left Ventricle Tip
- Left Ventricle Tip to Left Ventricle Ring
- Right Ventricle Tip to Right Ventricle Coil

It is indicated for use during chronic implantation of a pacing or defibrillation lead system.

Trained physicians and hospital staff will use the Model 6149 to assist with the implantation of a pacing or defibrillation lead system. No customer interaction will be required.

The Model 6149 is not intended to be part of the sterile field and has no sterilization requirements: It is for repeated use during implant procedures.

E. Intended Use Statement

The Model 6149 Pacing Vector Selector Cable Switch is a manually operated unit that connects to the Pacing System Analyzer (PSA) (3105) using a Redel connector.

It is used during lead implants for PSA measurements and provides the capability to switch RV and LV tip and ring signals to five possible electrode combinations.

F. Technological Characteristics Summary

As the Model 6149 is an accessory to ERA 300, the only difference is the Model 6149. The original and subsequent 510(k's) for the ERA 300 did *not* have and do *not* have an accessory such as the Model 6149.

In the same view, there are *no* similarities as the ERA 300 did *not* have such an accessory.
The addition of the Model 6149 to be used with Guidant's PSA Model 3105 is considered minor and does *not* raise any safety concerns or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administr.
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2005

Remington Medical, Inc.
c/o Mr. Don Rosvold
President
6830 Meadowridge Court
Alpharetta, GA 30005

Re: K050884
Guidant Model 6149 Pacing Vector Selector Patient Adapter Cable
Regulation Number: 21 CFR 870.3600
Regulation Name: External Pacemaker Pulse Generator
Regulatory Class: III (three)
Product Code: DTA
Dated: March 31, 2005
Received: April 7, 2005

Dear Mr. Rosvold:

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/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

Indications for Use

510(k) Number (if known): *To be determined* K050884

Device Name: Model 6149

Indications for Use:

- The Model 6149 Pacing Vector Selector Cable Switch is a manually operated unit used during lead implants for PSA measurements and provides the capability to switch RV and LV tip and ring signals to five possible electrode combinations.

Prescription Use _X__ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT 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 K050884