NOV 1 2 1999

K992863

510(k) SUMMARY

1. **Device Name:** Accessory Stylet Kit Models 6504, 6505, 6506, 6507

2. **Devices to Which Equivalence is Claimed:** With the exception of a difference in length, the stylets in the new accessory kits are identical to stylets currently packaged with leads (K893957, cleared 7/14/89 and K932103, cleared 12/8/93). With respect to packaging, the new accessory kits are identical to the currently marketed Accessory Stylet Kit Models 6501, 6502, 6503 and 6504 (K905674, cleared 1/30/91).

3. **Intended Use:**

   These stylets are wires intended to facilitate the placement of pacing leads during pacemaker implant procedures.

   The straight stylets are used to direct passage of a lead to the appropriate heart chamber and to wedge the lead in the trabeculae of the ventricle.

   The J-shaped stylets are used to direct passage of a lead in the atrium.

4. **Device Description:**

   The new accessory kits will allow separate packaging of lead stylets currently marketed with Guidant pace/sense and defibrillation leads. The stylets are provided in 0.014 and 0.016 inch diameters, with their respective "stiffness" labeled soft and firm. Each stylet package will contain two stylets of the same diameter. The stylets are made of chromium-nickel 304 stainless steel spring wire and have polypropylene Hercules PD 701 Knobs. The stylets are inserted into a coiled polyethylene stylet ring for packaging and ease of use purposes.

5. **Summary of Technological Characteristics:**

   This notification concerns the separate packaging of currently marketed stylets using packaging materials, configurations and processes identical to currently marketed accessory kits. There are no changes to the design, materials, manufacturing process, packaging process, sterilization process, or shelf life of the subject device.

6. **Summary of Substantial Equivalence:**

   The indications for use and packaging for the stylets are identical to the currently marketed stylets, Models 6501, 6502, 6503 and 6504 (K905674, cleared 1/30/91). All other aspects of the proposed accessory kits (Models 6505, 6506, 6507 and 6508)

are identical to the currently marketed stylets (K893957, cleared 7/14/89 and K932103, cleared 12/8/93)

7. Testing Data:

This notification concerns the separate packaging of currently marketed stylets using packaging materials, configurations and processes identical to currently marketed accessory kits. There are no changes to the design, materials, manufacturing process, packaging process, sterilization process, or shelf life of the subject device. Therefore, no additional testing was deemed necessary. Biocompatibility Testing and Design Verification Testing of previous stylets were referenced in support of the proposed accessory kits (P930060/S41, approved 9/20/96).

8. Conclusion:

The separate stylet accessory kits, Model 6504, 6505, 6506 and 6507 are substantially equivalent to the currently marketed Guidant stylet accessory kits (K905674, cleared 1/30/91) with regard to packaging materials, configurations, processing and sterilization. The stylets are identical to the stylets currently marketed with pacing leads (K893957, cleared 7/14/89 and K932103, cleared 12/8/93).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1999

Ms. Sheryl Poganski
Guidant Corporation
Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: K992863
Lead Stylet, Models 6505, 6506, 6507 and 6508
Regulatory Class: II (two)
Product Code: 74 DRB
Dated: August 24, 1999
Received: August 25, 1999

Dear Ms. Poganski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K992863

Device Name: Lead Stylet

Indications for Use:

These stylets are wires intended to facilitate the placement of pacing leads during pacemaker implant procedures.

The straight stylets are used to direct passage of a lead to the appropriate heart chamber and to wedge the lead in the trabeculae of the ventricle.

The J-shaped stylets are used to direct passage of a lead in the atrium.

(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)

for Witten

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992863