

K972484

SEP 26 2007

510(k) Summary
ACS VIKING™ Guiding Catheter

1. **Device Name:** ACS VIKING™ Guiding Catheter
2. **Devices to which Equivalence is Claimed:** ACS TOURGUIDE™ Coronary Guiding Catheter (K953987)
3. **Indication:** The ACS VIKING™ Guiding Catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced.
4. **Device Description:** The ACS VIKING™ Guiding Catheter is available in five diameters. The catheter has a standard length of 100 cm, but can be produced in lengths from 40 to 160 cm. The ACS VIKING™ Guiding Catheter is available in varying tip shapes. The guiding catheter has a radiopaque shaft, which varies in stiffness at the distal end. The catheter has a radiopaque soft tip and is available with or without side holes.
5. **Summary of Substantial Equivalence:** The indications, methods and conditions of use, packaging process and location, sterilization process and location, and bench test results of the subject device are identical to those of the currently marketed ACS TOURGUIDE™ Coronary Guiding Catheter (K953987). Moreover, the two catheters are similar in design and are composed of materials which have undergone biocompatibility testing showing acceptability for clinical use.
6. **Conclusion:** The ACS VIKING™ Guiding Catheter is substantially equivalent to the currently marketed ACS TOURGUIDE™ Coronary Guiding Catheter (K953987).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 1997

Mr. Judith P. Palin
Guidant Corporation
Advanced Cardiovascular Systems
3200 Lakeside Drive
P.O. Box 58167
Santa Clara, California 95052-8167

Re: K972484
ACS VIKING™ Guiding Catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: July 1, 1997
Received: July 2, 1997

Dear Ms. Palin:

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 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 requirement, 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) 594-4639. 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972484

Device Name: ACS VIKINGtm Guiding Catheter

Indications For Use: The ACS VIKINGtm Guiding Catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972484

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

CR

Over-The-Counter Use

(Optional Format 1-2-96)