DEC 0 4 2001

APPENDIX A - 510(K) SUMMARY

K013638

Submitter

Guidant Corporation
Vascular Invention
26531 Ynez Road, Temecula CA 92591

Contact: Nancy E. Ralston
Phone: (909) 914-6654, Fax: (909) 914-0339

Date

November 1, 2001

Device name

Device Trade Name:	VIKING OPTIMA™ Guiding Catheter
Device Common Name:	Percutaneous Catheter
Device Classification Name:	Guiding Catheter
Device Classification:	Class II
Product Code:	74 DQY

Summary of substantial equivalence

The design, materials, method of operation, and intended use features of the proposed (7F, 8F) VIKING OPTIMA™ Guiding Catheter are substantially equivalent with regard to these features in the predicate device, the VIKING OPTIMA™ Guiding Catheter, K001435.

Device description	The proposed (7F, 8F) VIKING OPTIMA™ Guiding Catheter has a standard working length of 100 cm and a standard overall length of 107 cm, but can be produced in lengths from 40 to 160 cm depending upon physician preference and patient size. The proposed (7F, 8F) VIKING OPTIMA™ Guiding Catheter has a radiopaque shaft, which varies in stiffness at the distal end to accommodate customer preference and give optimal support in each tip shape. The stiffness of the shaft is determined by the durometer of the segment of polymer along the axial length. The lower the durometer of polymer (or polymer blend of Nylon 12 and/or Pebax), the more flexible the guiding catheter. The Pebax raw material durometers vary from 25D to 72D. The guiding catheter also has a radiopaque soft tip at the most distal section. The proposed (7F, 8F) VIKING OPTIMA™ Guiding Catheter is manufactured in varying tip shapes. Each shape is specific for patient anatomy and physician preference, and therefore a wide range of shapes is available with and without sideholes.
Indications	The guiding catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced.
Technological characteristics	The proposed (7F, 8F) VIKING OPTIMA™ Guiding Catheter incorporates similar design, components, method of operation, and indication of the predicate device, the VIKING OPTIMA™ Guiding Catheter (K001435) with exception of the shape of the reinforcement wire.
Performance data	The substantial equivalence of the proposed (7F, 8F) VIKING OPTIMA™ Guiding Catheter has been demonstrated through data collected from non-clinical bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2001

Ms. Nancy E. Ralston
Regulatory Affairs Coordinator
Guidant Corporation
26531 Ynez Road
Temecula, CA 92591-4628

Re: K013638
VIKING OPTIMA™ Guiding Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous catheter.
Regulatory Class: Class II
Product Code: DQY
Dated: November 1, 2001
Received: November 5, 2001

Dear Ms. Ralston:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B - INDICATIONS STATEMENT

510(k) number (if known):	The 510(k) number has not been issued yet. K013638
Device name	VIKING OPTIMA™ Guiding Catheter
Indications	The guiding catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced.

(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) OR ____ Over-The-Counter (Optional Format 1-1-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013638