

K994229

Appendix A - 510(k) Summary

Submitter	Guidant Corporation, Vascular Intervention Advanced Cardiovascular Systems, Inc. 26531 Ynez Road, Temecula CA 92591 Contact: Stacey Simon Phone: (909) 914-2800, Fax: (909) 914-2146
Date	December 15, 1999
Device name	<u>Device Trade Name:</u> VERIPATH™ Peripheral Guiding Catheter <u>Device Common Name:</u> Percutaneous Catheter <u>Device Classification Name:</u> Guiding Catheter <u>Device Classification:</u> Class II
Summary of substantial equivalence	The design, materials, method of operation, and intended use features of the Guidant VERIPATH™ Peripheral Guiding Catheter are substantially equivalent with regard to these features in the predicate device, the ACS VIKING™ Guiding Catheter (K972484).
Device description	The VERIPATH™ Peripheral Guiding Catheter is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices such as balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices, etc.

Appendix A - 510(k) Summary, Continued

**Device
description,
Continued**

Guiding Catheter

The guiding catheter is a single lumen catheter that allows contrast medium injections and facilitates the intravascular passage of diagnostic and therapeutic devices into the vascular system.

The guiding catheter has a standard working length of 50 cm and a standard overall length of 56 cm, but can be produced in overall lengths from 40 to 80 cm, depending upon physician preference and patient size.

The guiding catheter is available in three diameters/French sizes (F), as follows: 6F (0.068" ID, 0.82" OD), 7F (0.078" ID, 0.93" OD), 8F (0.088" ID, 0.105" OD). The guiding catheter is available in varying tip shapes designed for peripheral use. Each shape is specific for patient anatomy and physician preference, and therefore a wide range of shapes is available.

Inner Catheter

Also included in the VERIPATH™ device package is an inner catheter. The inner catheter is a single lumen catheter with a luer at the proximal end and is recommended for use with the guiding catheter to aid in the introduction and withdrawal of the guiding catheter.

The inner catheter has a standard working length of 65 cm and a standard overall length of 67 cm, but can be produced in lengths from 55 to 95 cm depending upon physician preference and patient size. The inner catheter is straight and available in three diameters/French sizes (F), as follows: 6F (0.062" OD), 7F (0.072" OD), and 8F (0.082" OD) and may be sold either with or without a taper at the tip.

Appendix A - 510(k) Summary, Continued

Intended use	The peripheral guiding catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced into the peripheral vasculature.
---------------------	---

Indications statement	Please see above for intended use statement.
------------------------------	--

Technological characteristics	The Guidant VERIPATH™ Peripheral Guiding Catheter incorporates similar design, components, method of operation, and intended use of the predicate device, the ACS VIKING™ Guiding Catheter, with exception of the dimensions.
--------------------------------------	---

Performance data	The safety and effectiveness of the VERIPATH™ Peripheral Guiding Catheter have been demonstrated through data collected from nonclinical bench tests and analyses.
-------------------------	--



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 25 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Stacey Simon
Guidant Corporation
Vascular Intervention Group
26531 Ynez Road
Temecula, CA 92591-4628

Re: K994229
VERIPATH™ Peripheral Guiding Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: February 9, 2000
Received: February 10, 2000

Dear Ms. Simon:

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 (Pre-market 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.

Page 2 - Ms. Stacey Simon

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten for". The signature is fluid and cursive, written over the typed name.

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

GUIDANT

Indications for Use Statement

**510(k)
number
(if known):**

The 510(k) number has not been issued yet.

Device name

VERIPATH™ Peripheral Guiding Catheter

Intended Use

The peripheral guiding catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced into the peripheral vasculature.

The inner catheter is intended to provide support during the introduction and withdrawal of a guiding catheter.

Christy Sullivan, J.D. for Witten

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

(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)