

Attachment B - 510(k) Summary

Submitter	Guidant Corporation, Vascular Intervention Advanced Cardiovascular Systems, Inc. 26531 Ynez Road, Temecula CA 92591 Contact: Stacey Simon Phone: (909) 914-4527, Fax: (909) 914-6690
Date	May 26, 1999
Device name	<u>Device Trade Name:</u> COPILOT™ Bleedback Control Valve <u>Device Common Name:</u> Hemostatic Valve <u>Device Classification Name:</u> Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass <u>Device Classification:</u> Class II
Summary of substantial equivalence	The design, materials, method of operation, and intended use features of the Guidant COPILOT™ Bleedback Control Valve are substantially equivalent with regard to these features in the predicate device, the ACS .096" Rotating Hemostatic Valve (K854261).
Device description	<p>The COPILOT™ Bleedback Control Valve has a 0.096" (2.44 mm) inside diameter. This device has two seals that operate independently: the clamp seal and the bleedback control (BBC) seal. The clamp seal can be opened or closed by rotating the cap. Closing of the clamp seal allows for pressure injections up to 400 psi and also secures the diagnostic/interventional device in position within the vasculature.</p> <p>The BBC seal is a diaphragm seal that forms around diagnostic/interventional devices as they move into and out of the vasculature. This seal provides minimal fluid loss without restricting device movement. The BBC seal is open when the cap is pressed down, and closed when the cap is released. An open BBC seal allows air and fluid to be purged and allows the advancement/ withdrawal of diagnostic/interventional devices.</p>

Appendix B - 510(k) Summary, Continued

Intended use The COPILOT™ Bleedback Control Valve is intended to maintain hemostasis during the introduction/withdrawal and use of diagnostic/interventional devices.

Indications statement The COPILOT™ Bleedback Control Valve is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter < 0.096" during interventional procedures.

Technological characteristics The Guidant COPILOT™ Bleedback Control Valve incorporates similar design, components, method operation, and intended use of the predicate device, the ACS .096" Rotating Hemostatic Valve (K854261), with exception of the BBC valve. The Guidant COPILOT™ Bleedback Control Valve is provided with an inner diameter of .096".

Performance data The safety and effectiveness of the Guidant COPILOT™ Bleedback Control Valve have been demonstrated through data collected from nonclinical bench tests and analyses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Stacey Simon
Regulatory Affairs Coordinator
Guidant Corporation
26531 Ynez Road
Temecula, CA 92591

Re: K991102
Trade Name: COPILOT™ Bleedback Control Valve
Regulatory Class: II
Product Code: DTL
Dated: March 31, 1999
Received: April 1, 1999

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 (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

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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) 594-4586. 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 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,



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

Enclosure

Attachment A - Indications for Use Statement

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

The 510(k) number is K991102.

Device name

COPILOT™ Bleedback Control Valve

**Indications
for use**

The COPILOT™ Bleedback Control Valve is indicated for maintaining a seal around diagnostic/interventional devices with an outside diameter < 0.096" during interventional procedures.

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