

## Appendix A - 510(k) Summary

<b>Submitter</b>	GUIDANT CORPORATION Cardiac Rhythm Management 4100 Hamline Avenue St. Paul, MN 55112	
	Contact: Michael Husby, Sr. Regulatory Affairs Associate Tel: 651/ 582-5774, Fax: (651) 582-5134	
<b>Date</b>	November 30, 2001	
<b>Device name</b>	<u>Device Trade Name:</u>	LV-1 HEMOSTATIC 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
<b>Summary of substantial equivalence</b>	The design, materials, method of operation, and intended use features of the GUIDANT LV-1™ Bleedback Control Valve are substantially equivalent to those of the predicate device, the GUIDANT COPILOT™ Bleedback Control Valve (K991102).	
<b>Device description</b>	<p>The LV-1 HEMOSTASIS VALVE, Model 6789 is a delivery system accessory for use in the implant of a GUIDANT left ventricular (LV-1) lead through the coronary sinus. The tip of the valve attaches to the LV-1 lead terminal pin and maintains a seal. A side arm port allows the lumen seal to be flushed and a bleedback control seal allows the introduction of an appropriately sized guide wire through an inside diameter of 0.070" (1.8 mm) while providing a seal.</p> <p>The bleedback control seal is a diaphragm seal that forms around a guide wire as it moves into and out of the lead lumen, catheter, and vasculature. This seal restricts fluid loss without significantly inhibiting wire movement. The bleedback control seal is easily penetrated by the wire guide, a small plastic funnel accessory that facilitates the introduction of a guide wire.</p>	



MAY - 2 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Karen S. Alsop  
Pr. Regulatory Affairs Associate  
Guidant Corporation  
4100 Hamline Avenue N  
St. Paul, MN 55112

Re: K021282

Trade Name: LV-1 Hemostasis Valve  
Regulation Number: 21 CFR 870.4290  
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold fitting  
Regulatory Class: Class II (two)  
Product Code: DTL

Re: K021283

Trade Name: Guidant Balloon Catheter  
Regulation Number: 21 CFR 870.1200  
Regulation Name: Diagnostic Intravascular Catheter  
Regulatory Class: Class II (two)  
Product Code: DQO

Re: K021284

Trade Name: EASYTRAK® Guiding Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: II (two)  
Product Code: DQY

Re: K021285

Trade Name: HI-TORQUE® Guide Wires  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II (two)  
Product Code: DQX

Dated: April 17, 2002

Received: April 18, 2002

Dear Ms. Alsop:

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 enclosures) 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

Page 2 - Ms. Karen S. Alsop

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) 594-4646. 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,



Donna-Bea Tillman, Ph.D.  
Acting Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

# Appendix C - Indications for Use Statement

**Applicant:** GUIDANT CORPORATION

**510(k) Number (if known):** K021282

**Device Name:** LV-1 HEMOSTASIS VALVE

**Indications for Use:**

The LV-1 Hemostasis Valve with the Wire Guide is indicated for maintaining a seal around the LV-1 lead terminal pin while flushing the lead lumen and/or during introduction/withdrawal of interventional devices.

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X    
(Per 21 CFR 801.109)

OR

Over-The-Counter \_\_\_\_\_

*[Signature]*  
Division of Cardiovascular & Respiratory Devices  
510(k) Number   K021282