SEP 1 3 2002

K022880

APPENDIX A. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Telephone: (408) 845-1910
Fax: (408) 845-1855

B. Contact Person

Debbie Cogan
Regulatory Affairs Associate

C. Date Prepared

August 13, 2002

D. Device Name

Trade Name: Guidant Proximal Seal System
Classification Name: Vascular Clamp
Product Classification Code: DXC
Device Classification: Class II
Establishment Registration #: 2953359

E. Device Description

The Proximal Seal System is designed to create a hemostatic environment at the site of a proximal anastomosis during coronary artery bypass graft surgery, eliminating the need for a side-biter or cross clamp of the aorta and minimizing aortic manipulation. When used in conjunction with off-pump cardiac surgery the Proximal Seal System alleviates the need for any form of clamping. Additionally, the Proximal Seal System eliminates the need for clamping with the side-biter clamp during on-pump cardiac surgery.

F. Intended Use

The Proximal Seal System is intended for use by cardiac surgeons during CABG procedures to maintain hemostasis and to facilitate the completion of a proximal anastomosis without application of an aortic clamp.

G. Substantial Equivalence

Guidant proposes that the Proximal Seal is similar to and substantially equivalent to the Baladi Inverter (K980128) and the Novare Enclose anastomotic assist devices. The subject device is substantially equivalent to the predicate devices with regard to intended use, indications, device characteristics, method of use, labeling, materials, and safety features.

H. Device Testing Results and Conclusion

Guidant Cardiac Surgery performed bench testing and animal testing which included biocompatibility, sterilization, packaging, and functionality to confirm that the proximal Seal device is equivalent to the predicate devices. All bench testing results met specified requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Guidant Corporation
C/O Mr. P.N. Ruys
KEMA Medical
N.V. Kema
Utrechtseweg 310
NL-6812 AR Arnhem, The Netherlands

Re: K022880
Trade Name: Proximal Seal System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: August 13, 2002
Received: August 30, 2002

Dear Mr. Ruys:

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) 594-4646. 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,

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

Enclosure

APPENDIX E: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 022880

Device Name: Proximal Seal System

Indications For Use: The Proximal Seal System is intended for use by cardiac surgeons during CABG procedures to maintain hemostasis and to facilitate the completion of a proximal anastomosis without application of an aortic clamp.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022880

Prescription Use X OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(Optional Format 1-2-96)