K023630

APPENDIX A. 510(k) SUMMARY

FEB 2 0 2003

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

January 24, 2003

D. Device Name

Trade Name: ESSeX Aspiration/Irrigation Instrument with Positioning Guide
Classification Name: General & Plastic Surgery

E. Device Description

The ESSeX Aspiration/Irrigation Instrument with Positioning Guide is a reusable stainless steel irrigation/aspiration instrument with a positioning guide. The instrument is designed to for use during endoscopic surgical procedures.

The ESSeX Aspiration/Irrigation Instrument with Positioning Guide is manufactured from surgical grade stainless steel. The instrument has an overall operating length of 35.6cm and an outer diameter of 7.5 mm. The instrument functions as a standard suction/irrigator and provides for the localization and removal of a variety of irrigation, feeding, drainage, and chest

tubes. The positioning guide component of the instrument is attached in such a manner that allows for the delivery or capture of irrigation or drainage tubes.

F. Intended Use

The ESSeX Aspiration/Irrigation and Positioning Guide is intended for use by surgeons during endoscopic abdominal and thoracic surgical procedures to deliver and remove irrigation fluid to and from the operative site, localizing and removal of irrigation, feeding, drainage, and chest tubes.

G. Substantial Equivalence

Guidant Cardiac Surgery proposes that the ESSeX Aspiration/Irrigation Instrument with Positioning Guide is substantially equivalent to a Suction/Irrigator instrument (21 CFR 876.1500). The ESSeX Aspiration/Irrigation Instrument with Positioning Guide is substantially equivalent to the Karl Storz Suction/Irrigation Instrument. The comparison presented in the substantial equivalency table demonstrates that the subject device is substantially equivalent to the predicate device with regard to intended use, indications, device characteristics, and method of use, labeling, materials, and safety features.

H. Device Testing Results and Conclusion

All necessary testing will be performed on the ESSeX Aspiration/Irrigation Instrument with Positioning Guide and packaging to ensure that the product is substantially equivalent to the predicate devices and to ensure the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2003

Guidant Corporation
c/o Ms. Michelle Weidman
Office Assistant Coordinator
Kema Medical
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K023630
Trade/Device Name: Essex Aspiration/Irrigation Instrument with Positioning Guide
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 31, 2003
Received: February 3, 2003

Dear Ms. Weidman:

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), please contact the Office of Compliance at (301) 594-4659. 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) you may obtain. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX F. INDICATION FOR USE STATEMENT

510(k) Number (if known): K_____

Device Name: ESSeX Aspiration/Irrigation Instrument with Positioning Guide

Indications For Use:

The ESSeX Aspiration/Irrigation and Positioning Guide is intended for use by surgeons during endoscopic abdominal and thoracic surgical procedures to deliver and remove irrigation fluid to and from the operative site, localizing and removal of irrigation, feeding, drainage, and chest tubes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-9

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023630