510(k) SUMMARY OF SAFETY & EFFECTIVENESS

OCT - 1 1997

This 510(k) Summary details sufficient information to provide an understanding of the basis for a determination of substantial equivalence. For convenience, the summary is formatted pursuant to 21 CFR §807.92. This section may be used, as presented, to provide a substantial equivalence summary to anyone requesting it from the Agency.

21 CFR §807.92 a(1)

Submitter: ORIGIN® Medsystems, Inc.
135 Constitution Avenue
Menlo Park, CA 94025
(415) 617-5142
contact person: Anthony Durso
date prepared: July 10, 1997

21 CFR §807.92 a(2)

Trade name: Origin Ligator Device

Common name: Ligator
Classification name: Manual Surgical Instrument

21 CFR §807.92 a(3)

Identification of predicate(s): Substantial equivalence for the Origin Ligator Device is based on its similarities to predicate device: the ORIGIN AcuClip® Endoscopic Multiple Clip Applier, (K920599; 7/15/92),. It shares in material, and technological characteristics as the predicate device. The Origin Ligator Device is also similar in intended use.

21 CFR §807.92 a(4)

Device Description-parts and function/concept: The Origin Ligator Device is a single-use endoscopic device with dual functions of ligation and transection of isolated vessels and other structures. It consists of a tube, handle assembly, and located at the distal end of the tube is the cutting blade, grasping jaws, and a clip delivery system. The cutting blade is activated independently from the grasping jaws and the clip delivery system. The Origin Ligator Device will allow both clipping and cutting operations to be performed multiple times without removing the device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 1 1997

Ms. Cynthia G. Royster
Manager, Regulatory Affairs
ORIGIN Medsystems, Inc.
135 Constitution Avenue
Menlo Park, California 94025

Re: K972685
Trade Name: The Origin Ligator Device
Regulatory Class: II
Product Code: GCJ
Dated: July 10, 1997
Received: July 17, 1997

Dear Ms. Royster:

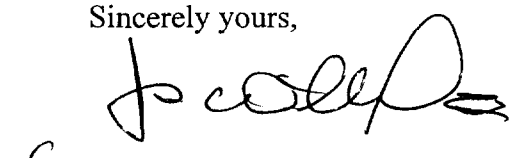
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) 594-4595. 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/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): ~~NA~~ K972685

Device Name: **The Origin Ligator Device**

Indications For Use: **has applications in open and endoscopic surgery. It is primarily indicated for patients undergoing endoscopic surgery that require ligation or ligation and transection of tissue including blood vessels, ducts and other structures in the extremies, extraperitoneal space, abdominal cavity and the chest wall. It is indicated for patients undergoing surgical procedures in the extremities including but not limited to saphaenous vein harvesting for peripheral or coronary artery bypass grafting.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Division Sign-Off) (Optional Format 1-2-96)

Division of General Restorative Devices

510(k) Number K972685