

K970611

ORIGIN Medsystems, Inc.
PREMARKET NOTIFICATION

Origin Cardiac Stabilizer Occluder
Class II

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

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)

AUG 19 1997

Submitter: ORIGIN® Medsystems, Inc.
135 Constitution Avenue
Menlo Park, CA 94025
(415) 617-5142
contact person: Anthony Durso
date prepared: February 13, 1997

21 CFR §807.92 a(2)

Trade name: To Be Determined

Common name: Clamp

Classification name: Vascular Clamp §870.4450

21 CFR §807.92 a(3)

Identification of predicate(s): Substantial equivalence for the Origin Cardiac Stabilizer Occluder is based on its similarities to the predicate device : the CardioThoracic System's (CTS) Stabilizer and Pilling's Micro Anastomosis Clamp. It shares the technological characteristics as the predicate devices. The Origin Cardiac Stabilizer Occluder is also similar in intended use.

21 CFR §807.92 a(4)

Device Description-parts and function/concept: This Origin Cardiac Stabilizer Occluder is a single use sterile device. It consists of a stabilizer foot, and occluders. The Origin Cardiac Stabilizer Occluder may be used by attaching the stabilizer foot to the Origin Cardiac Stabilizer Clamp; then this assembly is attached to a self retaining rib retractor or sternal retractor or other stationary platform. The Origin Cardiac Stabilizer Occluder may also be used by suturing the stabilizer foot to the desired area of the heart. The stabilizer foot rests against the epicardium. Forceps may be used to position

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the occluder over the desired vessel. Once in position the occluder may be advanced toward the vessel and locked in place; to cause the vessel to be temporarily occluded. Following completion of the surgical procedure , the Origin Cardiac Stabilizer Occluder is removed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

AUG 19 1997

Re: K970611
Origin Cardiac Stabilizer Occluder
Regulatory Class: II (two)
Product Code: DXC
Dated: June 16, 1997
Received: June 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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in

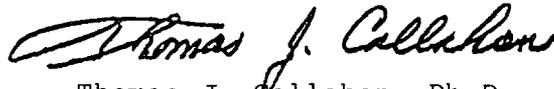
regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic 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) 594-4648. 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 at (301) 443-6597.

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

10(k) Number (if known): NA

Device Name: **Origin Cardiac Stabilizer Occluder**
Indications For Use: **The Origin Cardiac Stabilizer Occluder is indicated for use in cardiac surgery performed on the beating heart where local stabilization is required and a vessel may be temporarily occluded.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

(Optional Format 1-2-96)

Christina M. Abo for TJC

(Division Sign Off)
Division of Cardiac, Thoracic, Respiratory,
and Vascular Devices

510(k) Number K970611