K983744

JAN 21 1999

APPENDIX VIII
510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
26051 Merit Circle, Unit# 103
Laguna Hills, California 92653
(949) 582-6120 Ext. 310

CONTACT PERSON: Howard V. Rowe

DATE OF PREPARATION: October 22, 1998

NAME OF DEVICE: Applied Medical Modular Clip Applier System (MCAS)

CLASSIFICATION NAME: Cardiovascular Surgical Instrument 21 CFR 870.4500 Clip Applier, and 21 CFR 870.3250 Vascular Clip

TRADE NAME: Not established to date.

SUMMARY STATEMENT: The Applied Medical Modular Clip Applier System (MCAS) is substantially equivalent to the predicate Weck Closure System™ HEMOCLIP™ manufactured by Weck. The Applied Medical MCAS is a modular reposable device intended for ligation of tubular structures or vessels where a non-absorbable ligating device is indicated.

The reusable clip applier is made of stainless steel and is similar to standard clip appliers and surgical clamp designs currently on the market. The disposable clip cartridge is made of various plastic and metal materials and will be sold sterile. The clip cartridges will be available in four sizes, small, medium, medium/large, and large and will house six to ten titanium clips depending on the clip size to be used. The cartridges are color coded Yellow, Blue, Green and Orange respectively according to their size. The key difference between the Applied MCAS and the predicate device is the modular design which provides the user with multiple clips inside a cartridge which is loaded onto a reusable applier instead of manually loading individual clips into the applier during surgical procedures.

The Applied Medical Modular Clip Applier System passed all testing to demonstrate substantial equivalence to the predicate device and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1999

Mr. Howard V. Rowe
Director, Regulatory Affairs
Applied Medical Resources Corporation
26051 Merit Circle, Unit #103
Laguna Hills, CA 92653

Re: K983744
Trade Name: MCAS (Modular Clip Applier System)
Regulatory Class: II
Product Code: DSS
Dated: October 22, 1998
Received: October 23, 1998

Dear Mr. Rowe:

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 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). 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) 594-4586. 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 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX VII

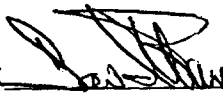
INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Applied Medical Modular Clip Applier System "Indication for Use" as required.

510(k) Number: Not Assigned

Device Name: Applied Medical Modular Clip Applier System

Indications for Use: The Applied Medical Modular Clip Applier System is indicated for ligation of tubular structures or vessels where a non-absorbable ligating device is indicated.

Signature:  Title: Director, Regulatory Affairs Date: 10-22-98

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 _____
(Per 21 CFR 801.109)

(Optional Format -2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983744