K992852

NOV 22 1999

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

CONTACT PERSON:

Anil Bhalani
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: November 19, 1999

NAME OF DEVICE: Suture Clinch

CLASSIFICATION NAME: Implantable Clip (21 CFR 878.4300)

TRADE NAME: Not Determined

SUMMARY STATEMENT:

The Suture Clinch fastens sterile non-absorbable sutures in sizes 0 to 4-0 USP by crimping the suture ends during soft tissue approximation. The Suture Clinch is manufactured from implant grade titanium. Its unique shape provides an optimum means of capturing and securing the suture. The unique shape of the Suture Clinch also allows the applicator (clip applier) to close the Suture Clinch completely around the suture. The Suture Clinch is available preloaded in a cartridge. The Suture Clinch Cartridge is designed to easily snap fit into the barrel of the applicator for application and quickly detach from the barrel after the clinch is applied to the suture. The single use Suture Clinch Cartridge is supplied sterile, packaged individually in a tyvek pouch.

The Applied Medical Suture Clinch is substantially equivalent to predicate devices 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

NOV 22 1999

Mr. Anil Bhalani
Director of Regulatory Affairs and
Clinical Programs
Applied Medical Resources
26051 Merit Circle, #104
Laguna Hills, California 92653

Re: K992852
Trade Name: Suture Clinch
Regulatory Class: II
Product Code: GCJ
Dated: August 20, 1999
Received: August 24, 1999

Dear Mr. Bhalani:

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 requirement, 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,

Neil R.P. Ogden for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K992852

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Suture Clinch "Indications for Use" as required.

510(k) Number: K992852

Device Name: Suture Clinch

Indications for Use: The Suture Clinch fastens sterile non-absorbable sutures in sizes 0 to 4-0 USP by crimping the suture ends during soft tissue approximation.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *11-19-99*

DRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992852

(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 _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)