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510(k) SUMMARY

510(k) NUMBER: K033024

SUBMITTED BY:

Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688
Phone: 949-713-8327
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CONTACT PERSON:

Cheryl Blake
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: October 16, 2003

NAME OF DEVICE: Suture Clinch

TRADE NAME: Not Determined

COMMON OR USUAL NAME: Suture Fixation Device

CLASSIFICATION NAME: Implantable Clip (21 CFR 878.4300)

SUMMARY STATEMENT:

Identification of the legally marketed: The Applied Medical Suture Clinch is substantially equivalent to the Applied Medical Suture Clinch cleared under Applied Medical's previous 510(k) filing number K992852.

Description:
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 poly acetyl plastic. 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 single use Suture Clinch Cartridge is supplied sterile, packaged individually in a Tyvek® pouch. The method of sterilization is EO with a Sal of 10^{-6}.

Intended Use: The Suture Clinch is a sterile single use clip intended fasten suture during laparoscopic surgery.

Non-clinical Testing: Bench top testing was conducted and comparisons were made to the predicated device.

Summary of Technological Characteristics: The Technological characteristics are the same as or equivalent to the predicated device and introduce no new safety and effectiveness issues when used as instructed. The polyacetal material used in the clinch is shown to be biocompatible according to ISO 10993-1 requirements.

Design Control / Risk Analysis/Design Verification: Design control, risk analysis and design verification activities for the subject of this Special 510(k) have been conducted in accordance with all applicable internal Applied Medical Procedures. The design control process employed is inclusive of the elements stipulated by 21 CFR § 820.30. The risk analysis preformed identified the risks relative to the performance requirements, as specified by Applied Medical internal procedures for risk analysis. The Design Risk Assessment Profile was conducted in accordance to Applied Medical internal Stand Operating Procedures, EN 1441 standards, ISO 9001/ISO 13485, AAMI/ISO TIR 14971, and 21 CFR § 820.30, validation and verification activities addressed the profile. Based on the risk analysis, validation and verification activities were formally controlled and addressed by Applied Medical, the activities included the methods, tests used, and acceptance criteria applied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2003

Ms. Cheryl Blake
Director of Regulatory Affairs
and Clinical Programs
Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K033024
Trade/Device Name: Suture Cinch
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: September 23, 2003
Received: September 26, 2003

Dear Ms. Blake:

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. 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 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,

for Miriam C. Provost

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

K033024

INDICATIONS FOR USE

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

510(k) Number: Unknown

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: *9-23-03*

Miriam C. Provost

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

510(k) Number K033024

(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 1-2-96)