NEW WAVE ENDO

M-CLOSE KIT - ITEM No. 27-101 is a convenience kit that includes multiple products.

1 - M-CLOSE SUTURING DEVICE:

A manual surgical instrument with suturing needles for passing ligature. It is a nonpowered, hand-held and designed for various general surgical procedures. The device also functions as needle guide that can inject and aspirate as well asa knot-tying instrument.

FDA REGULATORY CLASSIFICATION: CLASS 1 PER TITLE 21 SEC. 878.4800

FDA LISTING No.: D351694

1 - ANESTHESIA NERVE BLOCK NEEDLE KIT:

The Nerve Block Needle kit contains a Blunt Nerve Block Needle, a syringe and tubing. It is intended for the administration of local anesthetic agents to provide regional anesthesia for the purpose of reducing pain post operatively.

FDA REGULATORY CLASSIFICATION: CLASS 2

FDA 510K No.: K052946 (*PLEASE SEE ATTACHED*)

1 - PHMB TELFA DRESSING:

PHMB impregnated Telfa is a sterile, single use, wound dressing consisting of a non-adherent dressing treated with polyhexamethylene biguanide hydrochloride which has been shown to reduce wound infections.

FDA REGULATORY CLASSIFICATION: CLASS 2

FDA 510K # K070653 *(PLEASE SEE ATTACHED)*

DEC 8 2005 K052946

510(k) Summary

1. Submitter:

MPS Acacia
785 Challenger Street
Brea, CA 92821
Tel: 714-257-0470
Fax: 714-257-0513

2. Contact:

Fergie F. Ferguson, RA/QA Manager
MPS Acacia

3. Date prepared: October 18, 2005

4. Device trade name: Nerve Block Needle

   Common name: Nerve Block Needle

5. Predicate device: Blunt Nerve Block Needle
   510(k) number: K041843
   Marketed by: Epimed International
   141 Sal Landrio Drive
   Johnstown, NY 12095

   Predicate device: Pajunk Anesthesia Conduction Needle
   510(k) number: K040965
   Marketed by: Pajunk Medical Technology
   Karl-Hall-Str. 1
   78187 Geisingen
   Germany

   Predicate device: Plexolong Set
   510(k) number: K013041
   Marketed by: Pajunk Medical Technology
   Karl-Hall-Str. 1
   78187 Geisingen
   Germany

6. Description:

The MPS Acacia Nerve Block Needle consists of a stainless steel cannula with various tip types (Blunt, Housted, Touhy, Crawford, Quincke, Chiba, Sprotte, Freeman) and a molded plastic hub. A stylet is also provided consisting of a stainless steel shaft and a molded plastic hub.

The MPS Acacia Nerve Block Stimulating Needle version is electrically conductive at the distal end of the device.

The Nerve Block Needle will be provided as a sterile, single use, non-pyrogenic, disposable device and will be available in a variety of lengths and gauges.

The Nerve Block Needle may be packaged individually or as part of a kit consisting of a catheter, various syringe sizes, introducer, extension set, gauze sponge, sponge applicator, drape, absorbent towel, hospital wrap, sterile gloves, and other commonly used FDA approved accessories dependent on the application as determined by the clinician.

7. Intended Use:

The MPS Acacia Nerve Block Needle is intended for the administration of local anesthetic agents to provide regional anesthesia or the administration of anti-inflammatory medication to relieve chronic pain conditions, or to facilitate placement of a catheter.

The MPS Acacia Nerve Block Stimulating Needle version is also intended to aid in locating specific peripheral nerves or nerve plexuses for the precise delivery of local anesthetic agents or anti-inflammatory medication for the relief of chronic pain conditions or to provide regional anesthesia, or to facilitate placement of a catheter.

Routes of administration may include Peripheral nerve blocks, Sympathetic blocks, Selective nerve blocks, Intra-articular injections (i.e. Facet blocks), Interlaminar and Transforaminal approaches.

8. Technological comparison to predicate device:

The MPS Acacia Nerve Block Needle has similar physical and technical characteristics to the predicate devices.

9. Non-clinical test summary:

The submission is based upon similar physical characteristics and intended use to the predicate devices.

10. Conclusion:

The comparison between the predicate devices and the proposed device demonstrates that the MPS Acacia Nerve Block Needle is safe and effective and is substantially equivalent to the products currently being legally marketed by Epimed International, and Pajunk Medical Technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 8 2005

Mr. Fergie F. Ferguson
Regulatory Affairs/Quality Assurance Manager
MPS Acacia
785 Challenger Street
Brea, California 92821

Re: K052946
Trade/Device Name: MedFlo, MedFlo Pain Kit, MedFlo Nerve Block, MedFlo LI and MedFlo LI-KVO
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: October 18, 2005
Received: October 20, 2005

Dear Mr. Ferguson:

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

Applicant: MPS Acacia

510(k) NUMBER (IF KNOWN): ______________

DEVICE NAME: MedFlo, MedFlo Pain Kit, MedFlo Nerve Block, MedFlo LI and MedFlo LI-KVO

INDICATIONS FOR USE:

1. The MPS Acacia Nerve Block Needle is intended for the administration of local anesthetic agents to provide regional anesthesia or the administration of anti-inflammatory medication to relieve chronic pain conditions, or to facilitate placement of a catheter.
2. The MPS Acacia Nerve Block Stimulating Needle version is also intended to aid in locating specific peripheral nerves or nerve plexuses for the precise delivery of local anesthetic agents or anti-inflammatory medication for the relief of chronic pain conditions or to provide regional anesthesia, or to facilitate placement of a catheter.
3. Routes of administration may include Peripheral nerve blocks, Sympathetic blocks, Selective nerve blocks, Intra-articular injections (i.e. Facet blocks), Interlaminar and Transforaminal approaches.

Prescription Use XX (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter-Use _____ (Part 21 CFR 801 Subpart C)

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052946

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2007

Tyco Healthcare
% The Kendall Company
Mr. Paul W. Evans
Director, Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K070653
Trade/Device Name: Kendall Antimicrobial Drain Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 12, 2007
Received: June 14, 2007

Dear Mr. Evans:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070653

Indications for Use

510(k) Number (if known): K070653

Device Name: Kendall Antimicrobial Drain Dressing

Indications For Use: Over the counter use as a primary or secondary dressing for light to moderate draining wounds.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070653

SEP 12 2007

K070653

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510(k) Summary

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare
15 Hampshire St.
Mansfield, MA 02048
Date Prepared:

1. Contact Person:

Paul W. Evans
Director, Regulatory Affairs
(508) 261-8203

2. Name of Medical Device:

Classification Name: Dressing
Common or Usual Name: Kendall Kerlix AMD Antimicrobial Gauze Dressing (OTC)

3. Identification of Legally Marketed Device:

The Kendall Kerlix AMD Antimicrobial Gauze Dressing for OTC use is substantially equivalent in intended use, function, and composition to Kendall's AMD Antimicrobial Gauze Dressing (Rx) cleared by FDA under 510(k) No. K990530. The primary purpose of this 510(k) is to allow OTC retail marketing of this dressing. Labeling of the OTC product has been augmented to include added directions for use for a non-professional retail population.

4. Device Description:

The Kendall Kerlix AMD Antimicrobial Gauze Dressing is a sterile, single use, wound dressing consisting of gauze treated with polyhexamethylene biguanide hydrochloride, and is available in both sponge and roll form.

5. Device Intended Use:

The Kendall Kerlix AMD Antimicrobial Gauze Dressing is intended for OTC use. It is used as a primary dressing for exuding wounds, burns, as a cover for surgical wounds, and to secure and prevent movement of primary dressings.

K070653

2/2

6. Product Comparison

The Kendall Kerlix AMD Antimicrobial Gauze Dressing is equivalent to the referenced predicate device in that it is intended to be used as a wound covering, it contains an ingredient that enhances the bacterial barrier function of the dressing, and it has a broad spectrum of antimicrobial activity.

7. Nonclinical Testing

Biocompatibility testing of the predicate Kendall Kerlix AMD Antimicrobial Gauze Dressing has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1. The dressing subject to this submission is identical to the predicate device with the exception of OTC labeling.