OCT 2 6 2001

Medical Instruments Technology, Inc's
Reprocessed Tourniquet Cuffs Premarket Notification

Medical Instruments Technology Inc.

Quality Reprocessing and Surgical Cost Containment Systems

Section 12: 510k Summary

I. Name of Submitter

Medical Instruments Technology, Inc.
385 North 3050 East
Saint George, UT 84790
Tel: (435) 674-4010
Fax: (435) 674-9819

Contact persons: Tom Haueter, RA/QA Manager
Crystal Batcabe, Assistant RA/QA Manager

Summary Prepared August 10, 2001

II. Device name and Classification:

Common Name: Tourniquet cuff, Sleeve, Limb, Compressible
Classification: Class II per 21 CFR 878.5910

III. Predicate Device:

MIT's reprocessed compressions cuffs are substantially equivalent to: Instrumed, Color Cuff (K890014)

IV. Description of Device

Tourniquet cuffs are composed of either a plastic or cloth cover, over one or more plastic or rubber bladders. There are one or more plastic tubes leading from the bladder to a connector that attaches to a compressor. All work on the same principal, a compressor inflates the bladder(s) with air to restrict the blood flow in the limb during surgery.

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V. Intended Use:

The intended use of a tourniquet cuff is to restrict blood flow to a patient's limb during surgery.

VI. Technological Characteristics:

MIT's reprocessed tourniquet cuffs have the same technological characteristics as the Instrumed Color Cuffs (K890014). The materials used in the manufacture of the garments are not changed during the reprocessing process. Additionally, MIT does not change any part of the cuff that might affect its function.

Testing by MIT has shown that the reprocessed devices are substantially equivalent to the predicate in performance.

VII. Bio-Compatibility:

Because MIT does not change any of the materials in reprocessing, the biocompatibility of MIT's reprocessed tourniquet cuffs is equivalent to the original manufacturers'. MIT does wash the tourniquet cuffs to ensure that they are free of residual bioburden. The washing procedure utilizes cleaning agents, which have been chosen for their safety and effectiveness. MIT rinses all of the tourniquet cuffs after washing to ensure that no residual cleansers remain. Additionally, MIT packages the devices in an environmentally controlled room to ensure continued cleanliness of the devices.

MIT has validated the ETO sterilization system used. Additionally, MIT has performed residual ETO testing to ensure that residual ETO has been reduced to an acceptable level.

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VIII. Substantial Equivalence:

Physical Characteristics: Color, dimensions, damage

MIT compared the reprocessed tourniquet cuffs to the predicate device for the parameters above. In all cases the reprocessed devices were substantially equivalent to the new devices.

Performance Characteristics: Ability to hold pressure

MIT compared the reprocessed tourniquet cuffs to the predicate devices (for the parameters above) and in all cases the devices were substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

Mr. Jack Speer
President
Medical Instruments Technology, Inc.
385 North 3050 East
St. George, Utah 84790

Re: K012632
Trade/Device Name: Reprocessed Pneumatic Tourniquet Cuffs
Regulation Number: 878.5910
Regulation Name: Pneumatic tourniquet
Regulatory Class: I
Product Code: KCY
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Speer :

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.

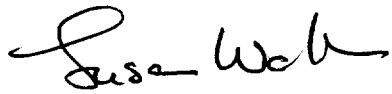
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

K012632

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Section 14: Indications for Use Statement

The intended use of a tourniquet cuff is to restrict blood flow to a patient's limb during surgery.

I certify that, in my capacity as PRESIDENT of MEDICAL INSTRUMENTS TECHNOLOGY, INC., the indications for use stated above are accurate and that the device will not be marketed for any other indications for use.

Jack Speer
(Signature)

Jack Speer, President MIT, Inc.
(Typed Name)

8-10-01
(Date)

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

510(k) Number K012632