Medical Instruments Technology Inc.

K012624

NOV 0 8 2001

Quality Reprocessing and Surgical Cost Containment Systems

Section 12: 510(K) Summary

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

Device Name and Classification

Common Name: Arthroscopic Instruments, Reprocessed Arthroscopic Instruments, Arthroscopic Shavers, Shavers, Arthroscopic Blades, Burs

Classification: Class II per 21CFR 888.1100

Predicate Device

MIT's reprocessed arthroscopic shavers are substantially equivalent to: Dyonics Shavers K833587

Description of Device

The arthroscopic blade is composed of stainless steel tubing with plastic connectors. A small tube is fitted within a larger tube. The distal ends of the tubes are serrated and/or sharpened. The proximal end of each stainless steel tube is insertion molded into plastic connectors. The inner tube is fitted into the outer tube. The inner tube rotates within the outer tube and creates a scissor action that cuts soft tissue in the arthroscopy procedure. The assembled arthroscopic blade is connected to a power device that is adjusted by the clinician to rotate the inner tubing during use at the selected RPMs. The

arthroscopic blade from the surgical site.

Depending on the size and configuration of the device, the inner tube may be fitted with a plastic sheathing, or copper bearings, may be plated with an alloy such as nickel/tin and may be lubricated to facilitate rotation within the outer shaft. In addition the inner and outer tubes must be straight with no bends or kinks to ensure adequate rotation of the shafts during use. Burs must be absent from the cutting edges to prevent inadequate rotation and freezing up of the inner shaft during use.

Intended Use

MIT's mechanized reprocessing of arthroscopy blades does not change their intended use. The arthroscopy blades are inserted into hand pieces to allow cutting of soft tissue in arthroscopy procedures. The blades are designed for use in a range of surgical procedures. They are supplied sterile.

Technological Characteristics

MIT's reprocessed arthroscopic devices have the same technological characteristics as the predicate devices. MIT does not change any of the design characteristics or materials during reprocessing. The only material change, that MIT does make, is that of the sheathing. The sheathing is replaced, because the original sheathing would be damaged in the reprocessing procedures. The replacement sheathing is substantially equivalent to the original sheathing, and actually acts as a better friction barrier than the new sheathing (as shown in free-spin test.)

MIT has shown that the reprocessed shavers are substantially equivalent to the predicate devices by performance of the free-spin test, the cut-test, and the shed test. Additionally, we have tested the device for substantial biocompatibility by performing the TOC test and the ETO residual test. In all tests, the reprocessed devices have been equal to, or better than, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

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

Re: K012624
Trade Name: Reprocessed Arthroscopic Blades
Regulation Number: 888.1100
Regulation Name: Arthroscope and Accessories
Regulatory Class: II
Product Code: HRX
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 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) 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,

Susan Walker MS

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

NOV 0 8 2001

510(k) Number (if known): K012624

Device Name: Arthroscopy Blades

Indications For Use:

Disposable Arthroscopy Surgery Blades are indicated for resection of soft and osseous tissues in large articular cavities, small articular cavities, and Functional Endoscopic Sinus Surgery (FESS). The FESS application is limited to those small blades, which are appropriate for the procedure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

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

510(k) Number K012624

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)