SEP 1 8 2002

K022744

Medical Device Services, Inc.

144 West Brigham Road, Bldg. E.
St. George, UT 84790

Tel: (435) 652-3073
Fax: (435) 652-3087

510(k) SUMMARY

Re: Medical Device Services	
501(K) Notification:	Reprocessed Used Disposable Arthroscopic Blades and Burs
Classification Name:	87HWE Powered Surgical Instruments & Accessories/Attachments.
Common/Usual Name:	Disposable Arthroscopic Bone Shavers
Proprietary Name:	Reprocessed Used Disposable Arthoscopic Blades and Burs
Establishment Reg. No.:	1724309
Device Classifications:	Class I per 21 CFR 878.482 - Powered Surgical Accessories.

Medical Device Services (MDS), intends to market Reprocessed Stryker and Dyonics Disposable Arthroscopic Blades/Burs that have been reprocessed. Reprocessing Stryker and Dyonics Disposable Arthroscopic Blades/Burs is performed by MDS to MDS protocols. "Reprocessed," means all operations performed to render a contaminated single-use device patient ready (*Enforcement Priorities for Single-Use Devices Reprocessed by Third Party Reprocessors and Hospitals*).

MDS believes that reprocessed single-use Stryker and Dyonics Arthroscopic Blades/Burs can be considered "reusable" as defined in the Food and Drug Administration Compliance Policy Guide #7124.16: they are able to withstand the necessary cleaning and sterilization process, the physical characteristics or quality of the device will not be adversely effected, and the device remains safe and effective for its intended use.

MDS Reprocessed Stryker and Dyonics Disposable Arthroscopic Blades/Burs are single use surgical devices used for resection of tissue within joint spaces under arthroscopic control.

MDS Reprocessed Stryker and Dyonics Disposable Arthroscopic Blades/Burs are composed of the same materials as currently marketed hand-manipulated Stryker and Dyonics Disposable Arthroscopic Blades/Burs sold new.

MDS Reprocessed Stryker and Dyonics Disposable Arthroscopic Blades/Burs are substantially equivalent to disposable arthroscopic blades/burs marketed by Smith & Nephew Dyonics under 510(k) Number K953695.

MDS claims that Reprocessed Stryker and Dyonics Disposable Arthroscopic Blades/Burs are able to withstand the necessary cleaning and sterilization process, the physical characteristics or quality of the device will not be adversely effected, and the device remains safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2002

Medical Device Services
c/o Mark Aldana
Adven Medical, Inc.
1001 Slaton Highway
Lubbock, Texas 79404

Re: K022744
Trade/Device Name: Reprocessed Used Disposable Arthroscopic Blades and Burs
Regulation Number: 878.4820
Regulation Name: Powered surgical instruments & accessories/attachments
Regulatory Class: Class I
Product Code: HWE
Dated: August 9, 2002
Received: August 19, 2002

Dear Mr. Aldana:

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" (21 CFR 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

510)k) Number: K022744

Device Name: Reprocessed Used, Disposable Arthroscopic Blades and Burrs

Indications For Use:

Arthroscopic blades and burs are single use instruments consisting of several tubes and designs. The inner blade rotation is driven by a motor.

Arthroscopy blades and burs are indicated for resection of tissue within joint spaces under arthroscopic control.

Medical Device Services intends to reprocess arthroscopy blades and burs. Reprocessing includes all the steps performed to make a contaminated single use device patient ready.

Only disposable, non angled arthroscopy blades and burs manufactured by Dyonics and Stryker, that are currently sold on the market (which have met premarket requirements by the original manufacturer for single use) will be reprocessed by Medical Device Services.

(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 K022744

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)