MEDISISS™

510(k) Notification:
MEDISISS Reprocessed
Arthroscopic Shavers and Burs

DEC 2 0 2011

Section 5: 510(K) Summary K113028

Submitter/ Owner	MEDISISS 2747 SW 6th St. Redmond, OR 97756
Contact Name	Joyce Elkins Director of Quality Assurance and Regulatory Affairs P: 541-923-3310 F: 541-923-3375 E: JElkins@MEDISISS.com
Date Prepared	October 7, 2011
Device Names	Proprietary Name: MEDISISS Reprocessed Arthroscopic Shavers and Burs Common Name: Arthroscope and Accessories
Classification	Arthroscope, Class II, 21 CFR 888.1100, product code HRX
Predicate Devices	K940075 Arthrex Shaver Blade Set K012536 SterilMed Reprocessed Powered Arthroscopic Accessories K012667 Reprocessed Arthroscopic Shapers
Device Description	Arthroscopic devices reprocessed by MEDISISS include burs and blades at the end of a long rod that rotates within a hollow stainless steel housing. The housing has an opening on one side of the distal end, allowing the cutting tip to resect tissue while protecting adjacent material with the housing on the opposite side of the bur or blade. This system attaches to a motorized hand piece that drives the internal bur or blade inside the outer housing and provides suction to pull the cut tissue away from the surgical site. Devices are provided sterile.
Intended Use	MEDISISS Reprocessed Shavers and Burs are powered arthroscopic accessories intended for use in orthopedic joint surgery.
Technological Characteristics	The technological characteristics of the subject devices are substantially equivalent to the predicate devices listed in this submission. The subject devices have the same functionality and very similar indications as the predicate devices.

Performance Testing	The functional characteristics of the subject devices have been evaluated and found to be equivalent to the predicate devices. The patient contacting materials are either identical to the materials of the predicate devices, or have been fully evaluated for biocompatibility and functionality.
Conclusion	Based on comparison of the indications for use, technological characteristics, and performance data to the predicate devices, MEDISISS Reprocessed Arthroscopic Shavers and Burs have been shown to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medisiss
% Ms. Joyce Elkins
Director of Quality Assurance and
Regulatory Affairs
2747 SW 6th Street
Richmond, Oregon 97756

DEC 2 0 2011

Re: K113028
Trade/Device Name: Medisiss Reprocessed Arthroscopic Shavers and Burs
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 22, 2011
Received: December 02, 2011

Dear Ms. Elkins:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

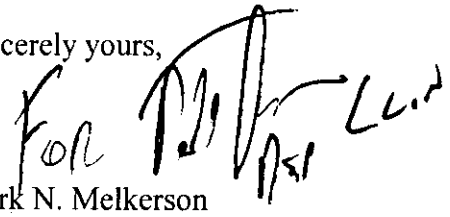
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

Section 4: Indications for Use

510(k) Number: ~~TBD~~ K113028

Device Name: MEDISISS Reprocessed Arthroscopic Shavers and Burs

Indications For Use:

MEDISISS Reprocessed Shavers and Burs are powered arthroscopic accessories intended for use in orthopedic joint surgery.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801.109) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113028