DePuy Mitek Inc. a Johnson & Johnson company — never stop moving

K131191

JUL 2 2 2013

510(k) SUMMARY

Submitter's Name and Address	Susan Kagan Project Manager, Regulatory Affairs DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767 Date Prepared: April 25, 2013	Telephone: 508-880-8097 Facsimile: 508-977-6911 e-mail: skagan@its.jnj.com
Name of Medical Device	Proprietary Name: Common Name:	FMS Shaver Blades and Burrs Blades and Burrs
Substantial Equivalence	Blades and Burrs for FMS Fluid Management System Shavers are substantially equivalent to the Blades and Burrs covered in the following cleared systems: • K954465 - FMS DUO pump and shaver system • K041824 – NeXtra™ arthroscopic pump and shaver system	
Device Classification	Classification Name: Arthroscope Classification Number: 21 CFR 888.1100 Class II Product Code: HRX	
Device Description	The purpose of this 510(k) Notification is to outline modifications made to the currently marketed FMS Blades and Burrs. The changes being made to the proposed devices are to enhance performance and include modifications including: material changes, modified inner and outer blade window profiles, and modified inner and outer burr tip geometry. FMS Shaver Blades and Burrs are used with the FMS™ Tornado or Micro Hand pieces which are accessories to the and Fluid Management Systems. They consist of stainless steel outer tube and a rotating inner tube connected to an inner and outer plastic hubs. Distal tips of the tubes contain sharp edges to facilitate the cutting.	
Indications for Use	The FMS Blades and Burrs are an accessory to the FMS Fluid Management Systems. FMS Blades and Burrs are intended to provide controlled cutting, burring, shaving and abrading of bone and tissue for use in arthroscopic	

	surgery.
Nonclinical Testing	Verification activities such as Blade Tissue Cutting, Burr Bone Cutting, Blade Shed Testing and Burr Shed Testing were performed on the proposed and predicate devices.
Safety and Performance	Results of performance and safety testing have demonstrated that the modified devices are substantially equivalent to the predicate devices. Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed Blades and Burrs have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DePuy Mitek Incorporated a Johnson & Johnson Company
% Ms. Susan Kagan
Project Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

July 22, 2013

Re: K131191
Trade/Device Name: Blades and Burrs for FMS Shavers
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: April 25, 2013
Received: April 26, 2013

Dear Ms. Kagan:

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 contact 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. 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 -S

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

Enclosure

INDICATION FOR USE STATEMENT

INDICATIONS FOR USE

510(k) Number (if known): K131191

Device Name: Blades and Burrs for FMS Shavers

Indications for Use: The FMS Blades and Burrs are an accessory to the FMS Fluid Management Systems. FMS Blades and Burrs are intended to provide controlled cutting, burring, shaving and abrading of bone and tissue for use in arthroscopic surgery.

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

Joshua C. Nipper -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131191