510(k) SUMMARY
Mitek Arthroscope

APR 1 8 2014

Recognized Manufacturer:
Medos International SarL
Puits Godet 20
CH 2000 Neuchâtel
Switzerland

Submitter:
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Name of Medical Device

Proprietary Name:	SwingScope
Classification Name:	Arthroscope
Common Name:	Arthroscope

Substantial Equivalence

Mitek Arthroscopes are substantially equivalent to the predicate devices listed in Table1.

Table 1: Predicate Devices

Company	Description	510(k)
Acclarent	Cyclops Multiangle Endoscope	K110097
Acclarent	Cyclops Multiangle Endoscope	K100577
Stryker	Stryker Arthroscope	K093677
Arthrex	Arthrex Arthroscopes	K030096

Device Classification	Classification:	Class II
	FDA Product Code:	HRX Arthroscope
	Regulation:	21 CFR 888.1100

Device Description

The Mitek Arthroscope is a multi-angle, rigid 4.3 mm arthroscope that has the capability of varying direction of view from 10° to 90° which enables surgeons to maximize and optimize their field of view inside the joint from any given port. This reduces the need for multiple fixed-angle arthroscopes.

The direction of view is altered by the direction of view dial; the direction of view is indicated by markings on the scope body. The Mitek Arthroscope provides a 55° field of view and a depth of field from 5mm to 40mm. The device shaft can also rotate by rotating the device (typically by the light post). A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source.

There are two light post stainless steel adaptors that accompany the Mitek Arthroscope. Two adapters are provided to facilitate connection with medical light source cables with a diameter of 5.0mm and smaller.

The Mitek Arthroscope is a reusable device and must be cleaned and sterilized according to the user manual prior to every use.

Indications for Use

Mitek Sports Medicine Arthroscopes are indicated for use in arthroscopic procedures (such as the knee, shoulder, hip, ankle, elbow) to provide visualization during surgery.

Non-Clinical Testing

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The Mitek Arthroscope does not differ from the predicate device in fundamental scientific technology or intended use.

Verification tests of the Mitek Arthroscope included performance, cleaning validation and biocompatibility to show that the device meets its product specifications over a range of operating conditions.

Safety and Performance

Verification testing conforms to the following Standards and Guidance documents listed in Table 2.

Table 2. Standards and Guidance Documents

Standard/ Guidance	Description
EN 60601-18	Medical electrical equipment -- Part 18: Particular Requirements for Basic Safety and Essential performance of endoscopic equipment
ANSI/AAMI/ISO 17665-1	Sterilization of Healthcare Products-Moist Heat-Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
ISO 11135-01	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
ISO 17664	Sterilization of medical devices. Information to be provided by the manufacturer for the processing of re sterilizable medical device
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
DIN ISO 8600-3:2004	Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics

Table 3 provides a summary of testing parameters and results.

Table 3. Summary of Testing

Test	Results
Field of View	Passed
Fixed Focus	Passed
Direction of View Range	Passed
Direction of View Torque	Passed
Rotation of View	Passed
Illumination	Passed
Scope Resolution	Passed
Visual Inspection	
Hermetic sealing	Passed

Free from aberrations	Passed

Results of performance testing have demonstrated that the proposed device is suitable for its intended use.

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed The Mitek Arthroscope has shown to be substantially equivalent to the 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

April 18, 2014

Medos International SARL - DePuy Mitek Incorporated
Ms. Susan Kagan
Project Manager Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K133941
Trade/Device Name: Arthroscopes (SwingScope)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: March 4, 2014
Received: March 10, 2014

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133941

Device Name: Mitek Arthroscopes

Indications for Use:

Mitek Sports Medicine Arthroscopes are indicated for use in arthroscopic procedures (such as the knee, shoulder, hip, ankle, elbow) to provide visualization during surgery.

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