K023777

4. 510(k) Summary

DEC 11 2002

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Manufactured by: Arthronet GmbH & Co. KG.
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Introduction

The Arthronet BLACKLINE Arthroscopic Blades are manufactured by Arthronet GmbH & Co. KG (formerly Imtec Medinzentechnik). The Blades are limited-use arthroscopic blade components (intended to be used three times, or until they are damaged/dull - whichever occurs first).

This product consists of either two or three components. The three-component product has an outer blade assembly, an inner blade, and an inner blade hub adapter. The two component product has an outer blade assembly and an inner blade assembly. The blade sets consist of six hub assembly configurations, and has both straight and curved blade configurations. Each configuration, except for the Arthronet 123 series, is designed to fit a specific FDA Cleared Arthroscopic Shaver System.

BLACKLINE Blade System

Arthronet Blackline Shaver Blade Series:	Hub Adapter Fits the following Shaver System:	Materials Used:	Equivalent to:
123	Arthronet (pending review and FDA clearance)	304 grade Stainless Steel and anodized aluminum for hub	Smith & Nephew Dyonics, Inc. Limited Reuse Arthroscopic Blades (K955914); Arthronet, Inc. Series 145/155 Blades (K003203)
133	Linvatec, Friatec, Arthrex Shaver Systems	304 grade Stainless Steel and anodized aluminum for hub	Smith & Nephew Dyonics, Inc. Limited Reuse Arthroscopic Blades (K955914); Arthronet, Inc. Series 145/155 Blades (K003203)
153	Dynonics EP 1	304 grade Stainless Steel and anodized aluminum for hub	Smith & Nephew Dyonics, Inc. Limited Reuse Arthroscopic Blades (K955914); Arthronet, Inc. Series 145/155 Blades (K003203)
163	Aesculap	304 grade Stainless Steel and anodized aluminum for hub	Smith & Nephew Dyonics, Inc. Limited Reuse Arthroscopic Blades (K955914); Arthronet, Inc. Series 145/155 Blades (K003203)
173	Stryker	304 grade Stainless Steel and anodized aluminum for hub	Smith & Nephew Dyonics, Inc. Limited Reuse Arthroscopic Blades (K955914); Arthronet, Inc. Series 145/155 Blades (K003203)
183	Storz	304 grade Stainless Steel and anodized aluminum for hub	Smith & Nephew Dyonics, Inc. Limited Reuse Arthroscopic Blades (K955914); Arthronet, Inc. Series 145/155 Blades (K003203)

Arthronet BLACKLINE Arthroscopic Blades are all made from 304 Stainless Steel and the adapter hubs are made from hardened anodized aluminum and stainless steel. These materials are essentially equivalent to those of predicate devices. Configurations and sizes are typical of predicate devices and indicated in catalog labeling.

Arthronet BLACKLINE Arthroscopic Blade assemblies consist of 2 piece and 3 piece blade assemblies, depending upon the shaver system they are used with. The 3 Piece blade consists of a single outer blade/hub assembly within which a two-piece inner blade and hub assembly can be inserted. The inner blade assembly snaps into place within the inner blade hub adapter. The resulting inner blade assembly, in turn, snaps into place within the outer blade assembly. The 2 Piece blade consists of a single blade/hub outer and a single inner blade/hub that are joined together in the identical fashion as the 3 Piece. The distal cutting orifices of the inner and outer blade assemblies align precisely to allow for rotary cutting as the inner blade rotates within the fixed outer blade. These assemblies are designed to facilitate cleaning and autoclave sterilization. Autoclave sterilization parameters are equivalent to predicate products noted and directions for use, cleaning and sterilization are contained in product labeling.

The Arthronet BLACKLINE Arthroscopic Blade configurations utilize materials similar to the predicate devices noted in the previous table. All predicate devices noted in this section have the same intended use.

The Arthronet BLACKLINE Arthroscopic Blades have been sold worldwide by Arthronet GmbH & Co. KG and their previous company for eight years and meet international product safety requirements. Submitted product intended for sale in the USA will also bear the CE mark and registration number of the Arthronet GmbH & Co. KG Notified Body and will also meet FDA product labeling requirements. Blades are identified with etched labeling noting the manufacturer and the country of manufacture.

The Arthronet BLACKLINE Arthroscopic Blades are essentially equivalent to the Arthronet Limited Use Arthroscopic Blades (such as the series 145/155 Blades, K003203) and the Smith & Nephew Dyonics Disposable Arthroscopic Blades (K953695) and the Smith & Nephew Dyonics Limited Use Arthroscopic Blades (K955914). Materials used are essentially equivalent and conform to many other surgical instruments.

Arthronet BLACKLINE Arthroscopic Blades are provided in a Non-Sterile condition. Recommended disassembly, cleaning, reassembly and sterilization instructions are identified and included in product labeling. These products are intended to be steam pressure autoclaved at cycle parameters equal to or exceeding 132°C and 2-bar pressure for 5 minutes. Cautionary warnings alert the user to thoroughly clean the units prior to sterilization and to remove all debris during the cleaning process. Cleaning and sterilization criteria are recommendations only and are based upon simulated use testing on file with the manufacturer. Labeling clearly indicate that hospitals should use their own validated cleaning and sterilization processes for these types of products.

Arthronet BLACKLINE Arthroscopic Blades are limited use devices. Blades are clearly labeled for use a maximum of three (3) uses. The blade assemblies can be discarded after three uses. Product usage and cautions related to potential damage to the blade assemblies as a result of handling or cleaning are clearly defined in product labeling. All product usage is based upon design data developed during product design, simulated use verification testing, and is also based upon seven years of clinical product experience in the worldwide market.

A complete risk analysis has been performed for these products and has been filed with the products' 510(k) submission. There were no identifiable risks associated with the use of this device that can be alleviated by product redesign.

The following table demonstrates the substantial equivalence of the Arthronet BLACKLINE Arthroscopic Blades to the following predicate devices:

Company:	Device:	Blade Material	Hub Adapter Material	Provided Sterile?	Recommen-ded Sterilization:	Intended Use:	Reusable?	Design:	510(k)
Arthronet GmbH & CO. KG	Limited Use Arthroscopic Blades and Hub Adapter	Surgical Grade Stainless Steel	Surgical Grade anodized aluminum	NO	Steam Autoclave	Joint Surgery (used with Arthronet, Dyonics EP1, Aesculap, Strkyer, Storz, Linvatec, Friatec and Arthrex external Shaver systems)	Blades are Limited Use (3 times).	Inner and outer tube with distal cutting	Pending
Arthronet, Inc.	Limited Use Arthroscopic Blades and Hub Adapter	Surgical Grade Stainless Steel	Surgical Grade Stainless Steel	NO	Steam Autoclave	Joint Surgery (used with Dyonics PS 3500/EP1, Linvatec, Concept and Arthrex external Shaver systems)	Blades are Limited Use (3 times); Hubs are reusable.	Inner and outer tube with distal cutting	K003203
Smith & Nephew Dyonics, Inc.	Limited Use Arthroscopic Blades	Surgical Grade Stainless Steel	Surgical Grade Stainless Steel	NO	Steam Autoclave	Joint Surgery (used with Dyonics PS 3500 Shaver system, or equivalent)	Limited Use	Inner and outer tube with distal cutting	K955914
Smith & Nephew Dyonics, Inc.	Disposable Arthroscopic Blades	Surgical Grade Stainless Steel	Surgical Grade Stainless Steel and Non-Autoclavable Plastic	Yes ETO sterilized by Manufacturer	Not intended to be resterilized	Joint Surgery	Single Use	Inner and outer tube with distal cutting	K953695
Micro-Aire Surgical Instruments, Inc.	Arthroscopic Surgical Blades (several models)	Surgical Grade Stainless Steel	Surgical Grade Stainless Steel and aluminum	NO	Steam Autoclave	Joint Surgery	Limited Use	Inner and outer tube with distal cutting	K901735

In all cases, the Arthronet BLACKLINE Arthroscopic Blades are essentially equivalent to the predicate devices noted. These products are intended to provide quality limited use surgical blade assemblies. Arthronet BLACKLINE Blades are equivalent to the Dyonics Limited Use Blades and the Arthronet, Inc. Series 145/155 Blades, where the device is discarded when they become dull or damaged. Arthronet BLACKLINE blades are intended to be used a maximum of three times, or until the blades are dull or damaged (whichever comes first). Strict tolerancing of blade assemblies allows for proper fit and cutting performance of replacement blades. Hub Adapters are designed to function with the shaver systems noted in product labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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DEC 11 2002

Arthronet Medical, Inc.
Carolina Schaber
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Irvine, California 92618

Re: K023777
Trade/Device Name: Arthronet Blackline Arthroscopic Blades
Regulation Number: 888.1100
Regulation Name: Arthroscope accessories
Regulatory Class: Class II
Product Code: HRX
Dated: November 5, 2002
Received: November 12, 2002

Dear Ms. Schaber:

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), 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. **Indications for Use**

The Arthronet BLACKLINE Arthroscopic Blades are indicated for minimally invasive joint surgeries, including but not limited to synovectomie, subacromial decompression, chondroplastic and ACL reconstruction.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023777