K060172

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

for

REMA Shaver Blades

February 20th, 2006

MAY 31 2006

1. Submitter Information:

a. Manufacturer/ Applicant:

Name:	REMA Medizintechnik GmbH
Address:	In Breiten 10 D-78589 Duerbheim- Tuttlingen Germany
Telephone:	0049 7424-4064
Fax:	0049 7424-501590
E-Mail:	info@rema-surgery.com

b. Correspondent:

Name:	Innovative Endoscopy Components, LLC
Address:	731-733 Shotgun Road Ft. Lauderdale, FL 33326
Telephone:	(954) 217-8780
Fax:	(954) 217-8781
E-Mail:	info@endoscopy.md

2. Device Name:

Classification Name:	Arthroscope Accessories
Classification Number:	888.1100 Class II
Proprietary Name:	REMA Shaver Blades

3. Predicate Device:

K023777, Arthronet Blackline Shaver Blades
K953695, Smith & Nephew Dyonics Arthroscopic Blades
K955914, Smith & Nephew Dyonics Arthroscopic Blades
K901735, MicroAire Surgical Blades
K963332, Stryker Shaver Blades
K943985, Linvatec Shaver Blades
K990524, Linvatec E9000 System
K041824, NeXtra Arthroscopic Shaver
K030009, Karl Storz Powershaver System S2

4. Description of Device:

   The REMA Shaver Blades consists of an outer tube with a hub and a rotating inner tube with a connector. The inner and outer tube consists of stainless steel. The hub and connector can consist of stainless steel or Polyphenylsulfone (PPSU). The components are designed and intended to be operated exclusively as a unit.

5. Indication for use:

   The REMA Shaver Blades are intended to provide shaving, cutting and abrading of bone and tissue during arthroscopic surgical procedures conducted by qualified surgeons.

6. Description of safety and substantial equivalence:

   The biological safety of the REMA Shaver Blades has been defined through the selection of materials that demonstrated appropriate levels of biocompatibility, which constitute the building blocks of the proposed device.
   These materials are similar or identical to those used for the manufacturing of the predicate devices as well as other brands legally sold in the USA.

7. Summary:

   Biocompatibility, function, indications and designs have been developed to ensure the safety of this device and it is substantially equivalent to commercially approved shaver systems available for sale in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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REMA Medizintechnik GmbH
% Innovative Endoscopy Components, LLC
Mr. Florian Gruber
731-733 Shotgun Road
Ft. Lauderdale, Florida 33326

Re: K060172
Trade/Device Name: REMA Shaver System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: May 18, 2006
Received: May 22, 2006

Dear Mr. Gruber:

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.

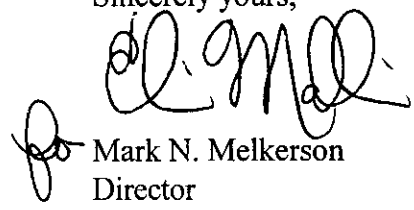
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K060172

Indications for Use

510(k) Number (if known): K060172

Device Name: REMA Shaver System

Indications For Use:

The REMA Shaver Blades are intended to provide shaving, cutting and abrading of bone and tissue during arthroscopic surgical procedures conducted by qualified surgeons.

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

(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 K060172