K031972 pg 1 of 2

510(k) Summary of safety and effectiveness

Applicant:
asap endoscopic products GmbH
Tullastr. 87 a
79108 Freiburg / Germany

Contact:
Dr. Martina Günderoth
C.R.C. Partnerschaftsgesellschaft
Katharinenstr. 5
23554 Lübeck, Germany

Phone: +49 (451) 388 2864
Fax: +49 (451) 388 2867
Email: crc@crc-online.de

Device name

Arthroscope, Types:	10-0001-00, 10-0002-00, 10-0003-00, 10-0004-00, 10-0005-00, 10-0006-00, 10-0007-00, 10-0008-00, 10-0009-00, 10-0091-00, 10-0010-00, 10-0011-00, 10-0085-00, 10-0012-00

Common name
Arthroscope

Predicate device name
- AMO Arthroscope (K962330)

Code of Federal Regulations (CFR) number
888.1100

General device description
The *asap arthroscope* is a rigid type endoscope with a new generation of compact objectives and a newly developed rod-lens system.

The basic design of the *asap arthroscope* is similar to those legally available for sale in the U.S.A.. It consists of an eyepiece and the body with light guide and rod-lens system. The body is designed of an outer and an inner tube of surgical steel. The light carrying fibers are sandwiched between these tubes. The inner tube of the body contains the rod-lens system.

Indications for use
Like the predicate device, the *asap arthroscope* is indicated for illumination during joint examinations, arthroscopies, biopsies and diagnosis of joint disease in minimally

K031972 pg 2 of 2

invasive procedures of the knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle and elbow.

The *asap arthroscope* is reusable.

The intended use for the asap arthroscope is – as prescribed in the manufacturers Instructions For Use – according to relevant medical indication by trained physicians only.

Voluntary standard compliance
The *asap arthroscope* complies with
- applicable portions of voluntary standards IEC 60601-2-18
- DIN 58105, part 1 and 2
- DIN 17442 (medical steel), as well as applicable portions of
- DIN 980

Substantially equivalence - Safety and effectiveness
The specifications and intended use of the *asap arthroscope* are the same to those of the claimed predicate devices. There are no significant differences between the asap arthroscope and the claimed predicates in design or conditions of intended use.

The *asap arthroscope* is constructed of materials of the same specifications as the predicate devices to ensure biocompatibility. The *asap arthroscope* conforms to applicable ISO standards.

The device will be sold non-sterile, to be sterilized prior to each procedure by the user. The ability to repeatedly adequately sterilize the devices has been confirmed by validation protocol.

Conclusion
In all respects, the *asap arthroscope* is substantially equivalent to one or more rigid endoscopes currently marketed in the USA. It is constructed of materials of the same specifications as the predicate devices to ensure biocompatibility and it conforms to applicable ISO standards.

The ability to repeatedly adequately sterilize the *asap arthroscope* has been confirmed by validation protocol.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2003

Dr. Martina Günderoth
Regulatory Affairs Manager
ASAP Endoscopic Products GmbH
c/o CRC
Katharinenstr. 5
23554 Lübeck, Germany

Re: K031972
Trade/Device Name: Arthroscopes, Types: 10-0001-00, 10-0002-00, 10-0003-00, 10-0004-00, 10-0005-00, 10-0006-00, 10-0007-00, 10-0008-00, 10-0009-00, 10-0091-00, 10-0010-00, 10-0011-00, 10-0085-00, 10-0012-00
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: June 18, 2003
Received: July 1, 2003

Dear Dr. Günderoth:

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. 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,

Miriam C. Provost

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

Enclosure

510(k) Number (if known): K031972

Device Name: asap arthroscope

Types: 10-0001-00, 10-0002-00, 10-0003-00, 10-0004-00, 10-0005-00, 10-0006-00, 10-0007-00, 10-0008-00, 10-0009-00, 10-0091-00, 10-0010-00, 10-0011-00, 10-0085-00, 10-0012-00

Indications For Use:

The *asap arthroscope* is indicated for illumination during joint examinations, arthroscopies, biopsies and diagnosis of joint disease in minimally invasive procedures of the knee, shoulder, wrist (carpal tunnel syndrome), temporal-mandibular joint, ankle and elbow.

The *asap arthroscope* is reusable and has to be sterilized prior to each procedure by the user.

The intended use for the *asap arthroscope* is according to relevant medical indication by trained physicians only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use

(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031972