K031974
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510(k) Summary of safety and effectiveness

SEP 2 9 2003

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

Contact:
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Device name

Hysteroscope, Types:	10-0018-00, 10-0019-00, 10-0020-00, 10-0021-00, 10-0022-00, 10-0023-00, 10-0024-00,
Gyn. Laparoscope, Types	10-0015-00, 10-0016-00, 10-0089-00,

Common name
Hysteroscope, Gyn. Laparoscope

Predicate device name
- Baho Hysteroscope (K # not available) and Galileo hysteroscope (K962256)
- Baho Gyn. Laparoscope (K982276)

Code of Federal Regulations (CFR) number
888.1690 and 884.1720

General device description
The asap hysteroscope and gynecologic laparoscope (herinafter: asap endoscope) 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 endoscope 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 hysteroscope* is used to illuminate and visualize the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

The *asap gynecologic laparoscope* is - like the predicate device - used to permit direct viewing of the organs wihin the peritoneal cavity for the purpose of performing diagnostic and surgical procedures.

Voluntary standard compliance
The *asap endoscopse* comply 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 endoscopes* are the same to those of the claimed predicate devices. There are no significant differences between the *asap endoscopes* and the claimed predicates in design or conditions of intended use.

The *asap endoscope* is constructed of materials of the same specifications as the predicate devices to ensure biocompatibility. The *asap endoscope* 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 endoscope* 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 endoscopes* 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 2 9 2003

Horst Baholzer
General Manager
asap endoscopic products GmbH
Tullastr. 87a
79108 freiburg
GERMANY

Re: K031974
Trade/Device Name: asap Hysteroscope, Models 10-0018-00, 10-0019-00, 10-0020-00, 10-0021-00, 10-0022-00, 10-0023-00, 10-0024-00; and, asap Gynecologic Laparoscope (Surgery), Models 10-0015-00, 10-0016-00, and 10-0089-00
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Product Code: 85 HIH
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Product Code: 85 HET
Regulatory Class: II
Dated: June 10, 2003
Received: July 1, 2003

Dear Mr. Baholzer:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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) you may obtain. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K031974**

Device Name: **asap Hysteroscope and gynecologic Laparoscope**

Indications For Use:

Hysteroscope: Provides illumination and visualization of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Gynecologic Laparoscope: Used to permit direct viewing of the organs within the peritoneal cavity for the purpose of performing diagnostic and surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031974

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)