OCT 7 1999

K992983
Pg 1 of 2

SUMMARY OF SAFETY AND EFFECTIVENESS

BAHO INNOVATIVE MEDIZINTECHNIK, GmbH
Autoclavable Cystoscopes

1) Submitter Information :

Name and Address :	Innovative Endoscopy Components, LLC 1112 Weston Road, PMB 227 Ft. Lauderdale, FL 33326
Telephone :	(954) 217-8780
Fax :	(954) 217-8781
E-mail :	IECflorida@aol.com
FDA Registration No.	1064152

2) Manufacturer Information :

	BAHO Innovative Medizintechnik GmbH Im Stoeckacker 7 D- 79224 Umkirch Germany
Telephone :	(011)49-7665-99094
Fax :	(011)49-7665-99095
FDA Registration No.	9615001
FDA Owner/Operator No.	9026517

3) Device Name :

Classification Name	Cystoscope Identical Materials,Components and Procedures as BAHO autoclavable Laparoscope 510(k) Number K982276
Classification Number	876.1500 (Class II Device)
Proprietary Name	BAHO autoclavable Cystoscope

4) Predicate Device : Storz Model # 27005
Wolf Model # 8650.../8660...

Manufacturer :	Karl Storz Mittelstrasse 8 Postfach 230 D-4200 Tuttlingen Germany	Richard Wolf Postfach 1164 D-75434 Knittlingen Germany

K992983
Pg 2 of 2

The above identified predicate devices have the basic design and technological features equivalent to those in the proposed BAHO autoclavable Cystoscope.

5) Description of Device :

The BAHO autoclavable Cystoscope has a basic design similar to those legally available for sale in the U.S.A. Like others legally sold in the U.S.A.,it consists of an eyepiece,body and insertion tube.The insertion tube is double walled surgical steel with illumination fibers in between. The insertion tube contains the optical rod lens system.(identical to BAHO autoclavable Laparoscope 510(k) Number K982276)

6) Indication for use :

Like the predicate devices,the BAHO autoclavable Cystoscope is indicated for use in the visual examination of body cavities, hollow organs and canals and using additional accessories, to perform various diagnostic and therapeutic procedures.

7) Description of safety and substantial equivalence :

The biological safety of the BAHO autoclavable Cystoscope 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 U.S.A. and other approved BAHO endoscopes (Arthroscope,Laparoscope)

8) Summary

In summary : biocompatibility, function, indications and designs have been developed to ensure the safety of this device.It is substantially equivalent to commercially approved cystoscopes available for sale in the U.S.A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1999

Mr. Gerald Goigitzer
Managing Director
Innovative Endoscopy Components, LLC
1112 Weston Road, Suite 227
Ft. Lauderdale, Florida 33326

Re: K992983
BAHO Autoclavable Cystoscope
Dated: August 21, 1999
Received: September 3, 1999
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FAJ

Dear Mr. Goigitzer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992983

Device Name: BAHO AUTOCLAVABLE CYSTOSCOPE

Indications For Use:

Like the predicate devices, the BAHO autoclavable Cystoscope is indicated for use in the visual examination of body cavities, hollow organs and canals and using additional accessories, to perform various diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992983