BEI MEDICAL SYSTEMS

MEDICAL SYSTEMS

83 Hobart Street
Hackensack, NJ 07601

Tel 201.489.4222
Fax 201.489.6745

K971492
P1071

SEP - 5 1997

PREMARKET NOTIFICATION [510(K)] SUMMARY

I.	Submitter:	BEI Medical Systems Company, Inc. 83 Hobart Street Hackensack, New Jersey 07601 (201) 489-4222 (phone) (201) 489-6745 (fax)
II.	Contact Person:	Lorraine T. Montemurro, RN Director, Regulatory Affairs & Quality Assurance
III.	Date:	April 24, 1997
IV.	Device Name:	Automatic Electronic Hysteroscopic Insufflator - AEH-200
V.	Common Name:	Hysteroscopic Insufflator
VI.	Classification Name:	Hysteroscopic Insufflator (per 21 CFR section 884.1700)
VII.	Equivalent Device:	Hamou Microhysteroflator - Karl Storz Hystero-Insufflator Electronic - Wisap
VIII.	Device Description:	This device is intended to distend the uterus by filling the uterine cavity with gas to facilitate viewing with a hysteroscope.
IX.	Intended Use:	The AEH-200 is intended to distend the uterus by filling the uterine cavity with CO_2 gas to facilitate viewing with a hysteroscope.
X.	Technological Summary:	This device has demonstrated compliance with the recommendations in the Draft: August 1, 1995 Submission Guidance for a 510(k) Submission on Hysteroscopic and Laparoscopic Insufflators. Specifically Sections II B through II F.
XI.	Nonclinical Performance: Data Summary	In house testing in accord with label claims demonstrated compliance. with these parameters.
XII.	Conclusion:	This device has proved comparable to similar devices already available and has not demonstrated any safety issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 1997

Ms. Lorraine Montemurro
Director, Regulatory Affairs & Quality Assurance
BEI Medical System Co., Inc.
83 Hobart Street
Hackensack, New Jersey 07601

Re: K971492
Automatic Electronic Hysteroscopic
Insufflator (AEH-200)
Dated: July 31, 1997
Received: August 1, 1997
Regulatory class: II
21 CFR §887.1700/Product code: 85 HIG

Dear Ms. Montemurro:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MEDICAL SYSTEMS

BEI MEDICAL SYSTEMS

83 Hobart Street
Hackensack, NJ 07601

Tel 201.489.4222
Fax 201.489.6745

510(k) Number (if known): New

Device Name: Automatic Electronic Hysteroscopic Insufflator

Indications For Use:

This device is intended to distend the uterus by filling the uterine cavity with CO_2 gas to facilitate viewing with a hysteroscope.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971492

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)