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Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	*Gynex Endospeculum* GYNEX Corporation

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

APR - 8 1998

1. Device Name:

Trade Name: ***Gynex Endospeculum***
Common Name: Endospeculum
Classification Name: Gynecological surgical forcep

2. Establishment Name & Registration Number:

Name: GYNEX Corporation
Number: 3032109

3. Classification:

§ 884.4530 Obstetric-gynecologic specialized manual instrument. (a) Identification. An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance. This type of device consists of the following: (1) An amniotome is an instrument used to rupture the fetal membranes. (2) A circumcision clamp is an instrument used to compress the foreskin of the penis during circumcision of a male infant. (3) An umbilical clamp is an instrument used to compress the umbilical cord. (4) A uterine curette is an instrument used to scrape and remove material from the uterus. (5) A fixed-size cervical dilator is any of a series of bougies of various sizes used to dilate the cervical os by stretching the cervix. (6) A uterine elevator is an instrument inserted into the uterus used to lift and manipulate the uterus. (7) A gynecological surgical forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination. (8) A cervical cone knife is a cutting instrument used to excise and remove tissue from the cervix. (9) A gynecological cerclage needle is a looplike instrument used to suture the cervix. (10) A hook-type contraceptive intrauterine device (IUD) remover is an instrument used to remove an IUD from the uterus. (11) A gynecological fibroid screw is an instrument used to hold onto a fibroid. (12) A uterine sound is an instrument used to determine the depth of the uterus by inserting it into the uterine cavity. (13) A cytological cervical spatula is a blunt instrument used to scrape and remove cytological material from the surface of the cervix or vagina. (14) A gynecological biopsy forceps is an instrument with two blades and handles used for gynecological biopsy procedures. (15) A uterine tenaculum is a hooklike instrument used to seize and hold the cervix or fundus. (16) An internal pelvimeter is an instrument used within the vagina to measure the diameter and capacity of the pelvis. (17) A nonmetal vaginal speculum is a nonmetal instrument used to expose the interior of the vagina. (18) A fiberoptic nonmetal vaginal speculum is a nonmetal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina. (b) Classification. Class II (performance standards).

Device Class: Class II
Classification Panel: Ob/Gyn Devices Panel
Product Code: 85HCZ

4. Preamendments Device:

1. Kogan Endospeculum, Gynecology, Obstetrics, V. Mueller, The Surgical Armamentarium, 1973., pp. 193.

5. Device Description:

General Description. The ***Gynex Endospeculums*** are made of 300 series instrument grade stainless steel. There are two styles, plain handle and ratchet handle. Both have "gold" plate handles. Tip sizes are 3mm and 4mm for both handle types. Overall length of both types is 270mm (approx. 10 in.). The device is essentially identical to the Kogan endospeculum listed above. The blade tips are spring closed and pressing the handles together opens spreads the tips to compress the cervical wall and expand the cervical os or urethra for inspection.

Intended Use. The endospeculum is used only to expand the scope of routine gynecological examinations. Fenestrated blades and finger rings bend outwards in opposite directions permitting thorough examination of the urethra and cervix. Compresses cervical tissue to allow direct visualization of the walls of the cervical os and interior of the uterus.

6. Applicant Name & Address:

GYNEX Corporation
16700 NE 79th St., Suite 204
Redmond, WA 98052

7. Company Contact:

Mr. Steve Angelo, President
GYNEX Corporation
16700 NE 79th St., Suite 204
Redmond, WA 98052
425.882.1179 * 425.895.0115 - fax

8. Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
1000 Burnett Av., Suite 450
Concord, CA 94520
510.356.2640 - 510.356.2654 - fax

9. Voluntary Standards:

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, GYNEX Corporation. Standard Operating Procedures (SOP), vendor certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

10. Comparison Table:

FEATURE	Gynex Endocervical Speculum	Pudendal/Paracervical Needle & Potocky Needle	SE?
Indications for Use(s):	Examination of the cervix and urethra	Examination of the cervix and urethra	YES
Design:	Plain & ratchet lock handles Spring closed Fenestrated tips	Plain handles Spring closed Fenestrated tips	Yes
Sterilization Method:	Steam Autoclave	Steam Autoclave	NO & YES
Sizes:	270mm long (± 10 in.) 3mm & 4mm tips plain & ratchet handle	9.75 in. long 3-4mm Plain handles	YES
Material:	302 Stainless steel	302 Stainless Steel	YES
Country of Origin:	Germany	Germany	YES
Manufacturer:	Gynex Corporation	V. Mueller	YES
Product Code:	84HCZ	84HCZ	Yes
K - Number:	Pending	Preamendment	YES

11. Storage, Packaging & Sterilization Information:

The *Gynex Endospeculums* are supplied in "clean only" condition and must be cleaned and sterilized prior to each use.

All packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. Any shipping damaged product should be returned promptly. Product for use in the operating room must be processed opened, handled and placed into use following accepted operating room sterile technique.

Remove all labels and packaging materials before cleaning and sterilization. Wash the *Gynex Endospeculums* thoroughly with hot water using a typical hospital grade surgical instrument detergent or soap. Ultrasonic cleaners may be employed. Cleaning, rinsing and sterilization must be performed in accordance with usual hospital practice before first or any subsequent use.

The recommended sterilization process for the instruments is steam autoclave sterilization. The recommended sterilization cycle is: saturated steam at 270° F for 30 minutes. This is the typical or usual steam sterilization cycle use for surgical instruments. Use of this cycle will produce a Sterility Assurance Level (SAL) of at least 10^{-6}. Validation of the recommended sterilization cycle will be achieved via the overkill method, the Kilmer method or a modified AAMI ST32 method 3, protocol B as selected by the biological testing laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gynex Corporation
c/o Mr. David W. Schlerf
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1000 Burnett Avenue
Suite 450
Concord, CA 94520

Re: K980237
Gynex Endospeculum
Dated: January 20, 1998
Received: January 23, 1998
Regulatory Class: II
21 CFR 884.4530/Procode: 85 KNA

APR - 8 1998

Dear Mr. Schlerf:

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 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,

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

510(k) Number (if known): K980237

Device Name(s):

GYNEX Endospeculum

Intended Use:

1. ***Endospeculum used only to expand the scope of routine gynecological examinations. Fenestrated blades and finger rings bend outwards in opposite directions permitting thorough examination of the urethra and cervix. Compresses cervical tissue to allow direct visualization of the walls of the cervical os and interior of the uterus.***

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Watkins
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980237

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)