3/12/99

K982739

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

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

1. Device Name:

Trade Name: ***Gynex Electrodes***
Common Name: cutting & coagulation electrodes
Classification Name: electrocautery, Gynecologic and accessories

2. Establishment Name & Registration Number:

Name: GYNEX Corporation
Number: 3032109

3. Classification:

§ 878.4120 Electrocautery, Gynecologic and accessories. (a) Identification. A gynecologic electrocautery is a device designed to destroy tissue with high temperatures by tissue contact with an electrically heated probe. It is used to excise cervical lesions, perform biopsies, or treat chronic cervicitis under direct visual observation. This generic type of device may include the following accessories: an electrical generator, a probe, and electrical cables. (b) Classification. Class II (performance standards).

Device Class: Class II

Classification Panel: OB/GYN

Product Code: HGI

4. Preamendments Device:

1. Cooper Surgical; Single-Use Tungsten Wire LEEP Electrodes, Sterile, K952483

Gynex Corporation Device	Equivalent Cooper Surgical Device
Curved electrode: 12cm x 1cm x 0.7cm	**Item #R1007 ZL:** 12cm x 1cm x 0.7cm
Curved electrode: 12cm x 1cm x 1cm	**Item #R1010 ZL:** 12cm x 1cm x 1cm
Curved electrode: 12cm x 1.5cm x 0.5cm	**Item #R1505 ZL:** 12cm x 1.5cm x 0.5cm
Curved electrode: 12cm x 1.5cm x 0.7cm	**Item #R1507 ZL:** 12cm x 1.5cm x 0.7cm
Curved electrode: 12cm x 2cm x 0.8cm	**Item #R2008 ZL:** 12cm x 2cm x 0.8cm
Curved electrode: 12cm x 2cm x 1cm	**Item #R2010 ZL:** 12cm x 2cm x 1cm
Square electrode: 12cm x 1cm x 1cm	**Item #S1010 ZL:** 12cm x 1cm x 1cm
Square electrode: 5.5cm x 1cm x .64cm	**Item #S1007 ZL:** 5.5cm x 1cm x 7.0mm
Ball electrode: 12cm x 5mm	**Item #B0512 ZL:** 12cm x 5mm
Ball electrode: 5.5cm x 5mm	**Item #B0555 ZL:** 5.5cm x 5mm

5. Device Description:

The *Gynex Electrodes* are made of thin 0.18mm hard tungsten wire with a high melting temperature and excellent conductiveness of electric current. The electrodes are available in three different styles intended for use in two different types of electrosurgical procedure. The three styles are curved wire loop electrodes, square wire loop electrodes and ball-type

electrodes. The two intended uses are excisional procedures (wire loop) and fulguration or coagulation procedures (ball electrode).

All electrode styles consist of an insulated conductive metallic shaft of varing length terminating in a bare metalic "ball" a "square wire loop" or a "curved wire loop". The wire loop electrodes vary in both width and depth of the loop. Electrode shaft diameter is constant at 2.5mm.

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.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - 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. Storage, Packaging & Sterilization Information:

Gynex brand *Electrodes* are supplied "STERILE". The sterilization method is EtO gas sterilization and the exposure cycle has been validated to achieve a sterility assurance level of 10^{-6}. The sterilization process, the validation procedure and the nature of the gas residuals are conducted and characterized in accordance with ANSI/AAMI/ISO 11135 –1994; EN550: 1994; AAMI method designation EOR; ISO/DIS 10993-7.2; FDA Proposed "Maximum Residue Limits and Maximum Exposure" and the Pharmacopeia of the United States.

Packaging materials are typical medical grade peel-type pouches of the generic mylar/non-woven sandwich variety. 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. Sterile product must be handled, opened and placed into use following accepted surgical sterile technique.

11. Comparison Table:

FEATURE	Gynex Disposable Electrodes	Cooper Surgical Single-Use Wire Electrodes	SE?
Intended Use:	Soft tissue cutting & coagulation Intraepithelial neoplasia Condylomata acuminata Misc. lesions; polyps, molluscum contagiosum, nevi, seborrheic keratosis, achricordon	Same	YES
Design:	Tugnsten wire Curved loop Square loop Brass ball electrode	Tugnsten wire Curved loop Square loop Brass ball electrode	YES
Sterile:	Yes	Yes	YES
Sizes:	**Curved electrode:** 12cm x 1cm x 0.7cm **Curved electrode:** 12cm x 1cm x 1cm **Curved electrode:** 12cm x 1.5cm x 0.5cm **Curved electrode:** 12cm x 1.5cm x 0.7cm **Curved electrode:** 12cm x 2cm x 0.8cm **Curved electrode:** 12cm x 2cm x 1cm **Square electrode:** 12cm x 1cm x 1cm **Square electrode:** 5.5cm x 1cm x 6.4mm **Ball electrode:** 12cm x 5mm **Ball electrode:** 5.5cm x 5mm Shaft diameter 2.5mm	**Curved electrode:** 12cm x 1cm x 0.7cm **Curved electrode:** 12cm x 1cm x 1cm **Curved electrode:** 12cm x 1.5cm x 0.5cm **Curved electrode:** 12cm x 1.5cm x 0.7cm **Curved electrode:** 12cm x 2cm x 0.8cm **Curved electrode:** 12cm x 2cm x 1cm **Square electrode:** 12cm x 1cm x 1cm **Square electrode:** 5.5cm x 1cm x .7cm **Ball electrode:** 12cm x 5mm **Ball electrode:** 5.5cm x 5mm plus additional size square, ball and needle-type electrodes Shaft diameter 2.5mm	YES
Material:	Tungsten wire Stainless steel Brass Teflon	Tungsten wire Stainless steel Brass Teflon	YES
Origin:	Europe	Europe	YES
Manufacturer:	Gynex Corporation	Cooper Surgical	YES
Product Code:	HGI	HGI	YES
K - Number:	Pending	K952483	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

Gynex Corporation
c/o Mr. David W. Schlerf
Official Correspondent
BUCKMAN Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389

Re: K982739
GYNEX Electrodes
Dated: November 20, 1998
Received: February 24, 1999
Regulatory Class: II
21 CFR 878.4120/Procode: 85 HGI

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 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 : K982739

Device Name(s):

GYNEX Electrodes

Intended Use of the Device:

1. Soft tissue cutting & coagulation
2. Intraepithelial neoplasia
3. Condylomata acuminata
4. Misc. lesions; polyps, molluscum contagiosum, nevi, seborrheic keratosis, achricordon, etc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982739/S001

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)