JAN - 7 2009

KARL STORZ ENDOSCOPY

K071754

510(K) SUMMARY

Sponsor/Submitter: Karl Storz Endoscopy-America, Inc.

Contact Person: Crystal Dizol
Regulatory Affairs Specialist
Email: cdizol@ksea.com

Date of Submission: June 26, 2007

Device Trade Name: Karl Storz Neo-vagina Surgery Set and Accessories

Common Name: Vaginal Dilator

Classification Name: Vaginal Stent

Regulation Number: 21 CFR 884.3900

Product Code: HDX

Predicate Device(s): Bioteque America, Inc. (K003380)
Specialities REMEEX International, S.L. (K033310)

Device Description: The KSEA Neo-vagina Surgery Set and Accessories is indicated for use by qualified surgeons to be placed in the vagina to enlarge the vaginal cavity and maintain the vaginal canal after laparoscopic-assisted creation of a neo-vagina.

Indications for Use: The KSEA Neo-vagina Surgery Set and Accessories is indicated for use by qualified surgeons in women with congenital absence of the vagina who have failed first-line non-surgical treatment with conventional vaginal dilators. The set is used in conjunction with a laparoscopic surgical procedure to create and enlarge the vaginal cavity via continuous traction between the abdomen and vulva, and to maintain the vaginal canal after surgery.

Technological Characteristics: The KSEA Neo-vagina Surgery Set and Accessories and its predicate devices are removable reusable devices, intended to enlarge the vagina by stretching and maintain vaginal patency. They are composed of biocompatible and autoclavable materials and are available in a range of sizes to meet the clinical and aesthetic needs of each case.

Summary of Substantial Equivalence: The KSEA Neo-vagina Surgery Set and Accessories is substantially equivalent to the predicate device since the basic features, design, and intended uses are similar. The minor differences between the KSEA Neo-vagina Surgery Set and Accessories and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function, or intended use of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2009

Ms. Crystal Dizol
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
CULVER CITY CA 90230-7600

Re: K071754
Trade/Device Name: KSEA Neo-vagina Surgery Set and Accessories
Regulation Number: 21 CFR §884.3900
Regulation Name: Vaginal stent
Regulatory Class: II
Product Code: HDX
Dated: December 29, 2008
Received: December 30, 2008

Dear Ms. Dizol:

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 such 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K071754

Device Name: KSEA Neo-vagina Surgery Set and Accessories

Indications for Use: The KSEA Neo-vagina Surgery Set and Accessories is indicated for use by qualified surgeons in women with congenital absence of the vagina who have failed first-line non-surgical treatment with conventional vaginal dilators. The set is used in conjunction with a laparoscopic surgical procedure to create and enlarge the vaginal cavity via continuous traction between the abdomen and vulva, and to maintain the vaginal canal after surgery.

Prescription Use: ✓ AND/OR Over-The-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071754