AUG 27 2003

K030693

KENTRON HEALTH CARE, INC
3604 KELTON JACKSON ROAD
P.O. BOX 120
SPRINGFIELD, TN 37172

Email: Kenorex@aol.Com
Phone: 615-384-0573
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Premarket Notification
510K Summary of Safety and Effectiveness
KENTEX Disposable Vaginal Speculum

Company Information:
KENTRON HEALTH CARE, INC
3604 KELTON JACKSON ROAD
SPRINGFIELD, TN 37172

CONTACT: NARI SADARANGANI, MD

SUMMARY PREPARATION DATE: MARCH 4, 2003

DEVICE INFORMATION:

TRADE NAME:	KENTEX DISPOSABLE VAGENAL SPECULUM
COMMON NAME:	DISPOSABLE VAGINAL SPECULUM
CLASSIFICATION NAME:	NON METAL VAGINAL SPECULUM
CLASSIFICATION PANEL:	OBSTRETICS AND GYNECOLOGY
REGULATION NUMBER:	21CFR PART 884.4530
CLASS	11
PRODUCT CODE:	HIB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2003

Sadarangani, MD, FACC, FCCP
President
Kentron Health Care, Inc.
3604 Kelton Jackson Road
P.O. Box 120
SPRINGFIELD TN 37172

Re: K030693
Trade/Device Name: Kentex Disposable Vaginal Speculum
Regulation Number: 21 CFR 884.4530
Regulation Name: Obtsetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 HIB
Dated: June 23, 2003
Received: July 30, 2003

Dear Dr. Sadarangani:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K030693/A1

510(k) NUMBER (IF KNOWN): K030693

DEVICE NAME: KENTEX VAGINAL SPECULUM DISPOSABLE

INDICATIONS FOR USE:

KENTEX DISPOSABLE VAGINAL SPECULUM IS INTENDED TO BE USED FOR GENERAL GYNECOLOGICAL PROCEDURES. IT IS INSERTED INTO THE VAGINA TO EXPOSE THE INTERIOR OF THE VAGINA.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Lepson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030693

SK 5-4