K082349

NOV 21 2008

510(k) Summary

Submitted by: J. Jamner Surgical Instruments, Inc.
9 Skyline Drive
Hawthorne, NY 10532

Contact Person: Jennifer Bosley, Regulatory Affairs Manager
Integra Medical Instrument Group
C/o Miltex, Inc.
589 Davies Drive, York, PA 17402 USA
Phone: (717) 781-6392
Fax: (717) 840-3509

Date Prepared: October 2, 2008

510(k) Number: **K082349**

Device Trade Name: JARIT® Hulka Uterine Tenaculum Forceps
Common/Usual Name: Uterine Tenaculum
Proposed Classification: Obstetric-gynecologic specialized manual instrument
21CFR§884.4530(a)(15) Class II, 85HDC

Device Description:

JARIT Hulka Uterine Tenaculum Forceps are an 11-inch long stainless steel, ring-handled instrument with ratchet closure having a single-tooth hook at the distal end of one arm and a 3.6 mm diameter uterine sound probe at the distal end of the other arm. The device is reusable, sterilizable and packaged non-sterile.

Indications for Use:

JARIT Hulka Uterine Tenaculum Forceps are indicated to stabilize the cervix and manipulate the uterine fundus under direct pelviscopic visualization in women whose uteri are anteverted or retroverted.

Predicate Devices:

510(k) #	Device	Manufacturer
Preamendment	JARIT Braun Uterine Tenaculum Forceps	J. Jamner Surgical Instruments
Preamendment	Hulka Tenaculum	Pilling Weck Surgical

Substantial Equivalence:

The JARIT Hulka Uterine Tenaculum Forceps are substantially equivalent to the legally marketed predicate devices. The devices have the same intended use, design, materials and processing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2008

Ms. Jennifer Bosley
Regulatory Affairs Manager
Integra Medical Instrument Group – Miltex
J. Jamner Surgical Instruments, Inc.
9 Skyline Drive
HAWTHORNE NY 10532

Re: K082349
Trade/Device Name: JARIT® Hulka Uterine Tenaculum Forceps
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HDC
Dated: October 2, 2008
Received: October 3, 2008

Dear Ms. Bosley:

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: K082349

Device Name: JARIT® Hulka Uterine Tenaculum Forceps

Indications for Use:

JARIT® Hulka Uterine Tenaculum Forceps are indicated to stabilize the cervix and manipulate the uterine fundus under direct pelviscopic visualization in women whose uteri are anteverted or retroverted.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use_____ (Part 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 K082349