MAR - 8 2004

K032091

510(K) SUMMARY

Date: 19 June 2003

Submission Correspondent: Emergo Group, Inc.

Address: 1684 East Gude Drive, Suite 202
Rockville, MD 20850

Phone: (301) 762-2828
Fax: (301) 762-4043

Contact: Mr. Rene van de Zande

Trade Name: Smart Klamp®
Common Name: Clamp, Circumcision
Classification: Obstetric-Gynecologic Specialized Manual Instrument

Description: The Smart Klamp® is a device composed of two components; a transparent plastic conic tube, and a plastic whit/off white clamping mechanism. The device is sold sterile for single use, packaged with a disposable sizing guide in a sterile pouch. The Smart Klamp® is available in multiple sizes, to accommodate newborn to adult patients.

Intended Use: The Device is indicated for Circumcision of newborns and older males, defined as circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus, with minimal amount of preputial skin remaining.

Predicate Devices: The predicate devices referenced in this submission are: the Kilejian Circumcisor, Gomco Circumcision Clamp, Mogan Circumcision Clamp, and Hollister Plastibell.

Summary and Conclusions Regarding Substantial Equivalence:
By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The differences between the Smart Klamp® and the predicate devices cited do not raise any different questions regarding safety and effectiveness. The differences in the technological characteristics are minimal, and the associated procedures are nearly identical. The indications for use are identical to the indications of one of the previously cleared predicate devices.

The device, as designed, is as safe and effective as the predicate devices, and the device is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2004

Mr. René van de Zande
Official Correspondent
Emergo Group, Inc.
2454 McMullen Booth Road, Suite 427
CLEARWATER FL 33759

Re: K032091
Trade/Device Name: Smart Klamp® Circumcision Clamp
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 HFX
Dated: December 9, 2003
Received: December 9, 2003

Dear Mr. van de Zande:

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 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

510(k) Number (if known): K032091

Device Name: **Smart Klamp®**

Indications for Use:

Circumcision of newborns and older males, defined as circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus, with minimal amount of preputial skin remaining.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032091

(Optional Format 3-10-98)

(Posted July 1, 1998)