K063429

510(K) Summary

Introduction

This 510(k) summary documentation is intended to comply with requirements of 21 CFR § 807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510K Submitted By

Generic Medical Device, Inc.
2201-34th Ave NW
Gig Harbor, WA 98335

JAN 17 2007

USA Contact Person

Monica R. Montanez, RAC, CQA
Consultant
Tel: 713-523-9630 / Fax: 713-521-2770

Date Prepared

November 5, 2006

Trade Name of Device

GMD Universal Circumcision Clamp

Proprietary Name:

GMD Universal Circumcision Clamp

Common Name:

Clamp, Circumcision

Classification Name:
Clamps, Circumcision
Class II: Obstetric-gynecologic specialized manual instrument
21 CFR 884.4530, Product Code HFX.

Predicate Devices:
K894201 – GOMCO Circumcision Clamp
Manufactured by:
Zinnanti Surgical Instruments
21540-B Prairie Street
Chatsworth, California 91311

510(k) Classification
Class II

Device Description

The GMD Circumcision Clamp is a stainless steel reusable medical device intended to be used in circumcision procedures. The GMD Circumcision clamp will be sold non-Sterile.

Intended Use
The GMD Circumcision Clamp is intended to be used in the medical procedure of circumferential excision of the foreskin or prepuce skin at or near the level of coronal sulcus, with minimal amount of preputial skin remaining.

Comparison to Predicate Devices
GMD Universal Circumcision Clamp has the same intended use, same technological characteristics as the predicate device (GOMCO Circumcision Clamp- K894201). The GMD Universal Circumcision Clamp and the GOMCO device are substantially equivalent in their method of circumcision as they both crush the prepuce parallel to the axis of the penis. They are also equivalent in intended use as they are both are used for circumferencial crushing of the prepuce to achieve circumcision.

Clinical/Non-Clinical Studies
The company did not conduct, nor depend on, clinical studies or non-clinical laboratory studies in order to establish substantial equivalence as this type of technology and procedure has a long history of clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Generic Medical Device Company
c/o Ms. Monica Montanez
Consultant
Montanez and Associates
3906 Roseland St.
HOUSTON TX 77006

JAN 17 2007

Re: K063429
Trade/Device Name: GMD Universal Circumcision Clamp
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HFX
Dated: November 11, 2006
Received: November 13, 2006

Dear Ms. Montanez:

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 (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 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). 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,

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

Indications for Use
GMD UNIVERSAL CIRCUMCISION CLAMP

510(k) Number (if known): K063429

Device Name: GMD Universal Circumcision Clamp

Indications For Use: The GMD Circumcision Clamp is intended to be used in the medical procedure of circumferential excision of the foreskin or prepuce skin at or near the level of coronal sulcus, with minimal amount of preputial skin remaining.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K063429