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510(K) SUMMARY

[as required by section 807.92(c)]

PrePex

510(k) Number K103695

Date:
January 6, 2012

Applicant Name:
Circ MedTech
6 Hahoshlim St, First floor
P.O Box 12006, Herzeliah 46722 Israel
Phone: +972 7 76935607
Fax: +972 7 76935601

Company Contact:
Alon Kushnir, VP Regulations and Clinical Affairs
Phone: +972 7 76935607
Email: alon@c-medtech.com

Contact Person:
Shoshana (Shosh) Friedman, RAC
Address: 1914 J N Pease Pl., Charlotte, NC 28262
Telephone: 704-430-8695 or 704-899-0092
Fax: 704-899-0098
E-mail: shosh@pushmed.com

Trade Name:
PrePex

Classification Name:
Clamps, Circumcision, Obstetric-gynecologic specialized manual instrument

Classification:
FDA has classified circumcision clamps for specific uses as class II devices (product code HFX) and they are reviewed by the Obstetric-Gynecologic review committee.

Reason for Submission:
New device

Predicate Devices:
Smart Klamp* Circumcision Clamp (Emergo Group, Inc.) cleared under K032091

Device Description:

The PrePex is a device composed of three components; a plastic Inner Ring, an Elastic outer clamping Ring and a Placement Ring for applying the clamping Elastic Ring. The PrePex System is sold sterile for single use and is available in multiple sizes to accommodate variances in adult patients. A sizing guide is separately available, sold clean for single use

Intended Use:

PrePex is indicated for circumcision of adult males. PrePex is intended to be placed and removed by a health care professional trained in male circumcision and in use of the PrePex device.

Technological Characteristics:

The device is designed to block blood supply to the foreskin by clamping the foreskin between the outer Elastic Ring and the Inner Ring. The device remains on the patient foreskin until the physician determines to remove the foreskin. This can be immediate, after placing the device and up to 1 week later when the device is removed.

Performance Pre-Clinical Data:

- The PrePex has been subject to biocompatibility testing per ISO 10993-1:2009 and FDA Blue Book Memorandum #G95-1 (cytotoxicity, dermal irritation, dermal sensitization). The results of these tests were negative and support the safe use of the PrePex in contact with non-intact skin.
- The PrePex successfully passed a series of bench tests including Delivery Ring Test, Elastic Ring Elongation Test, Inner Ring Surface Smoothness Test, and Final Product Measurements Test.

Performance Clinical Data:

- The PrePex Device was subject to a clinical study initiated and sponsored by the government of Rwanda. The objectives of the study were to assess the safety and efficacy of the PrePex Device for nonsurgical circumcision in adult males. A total of 50 healthy uncircumcised men aged 18 to 35 years were enrolled. The device was placed and removed by a physician or a nurse in a non-sterile setting, with no need for anesthesia or suturing. The subjects were seen regularly throughout the 6-week study, with pain assessed using a visual analog scale (VAS) at each visit.
  The results of this study show that all subjects achieved the endpoint of complete circumcision with no cases of bleeding and no unexpected adverse events related to the procedure or the device. Only 1 case of diffuse edema, which was resolved with minimal intervention (Ibuprofen), was reported following device removal. All subjects returned to their daily routines soon after device placement and removal, with no sick/absent days associated with the procedure. The median time for complete healing was 21 days after device removal, i.e., 28 days post-placement; the mean time was 25.3 days after device removal. There were no device-related incidents, the device functioned as expected in all subjects and there were no instances of erroneous placements of the device.

- As a result of the above mentioned study, the Government of Rwanda sponsored a second study in which the performance of the PrePex device was compared to a WHO approved method of surgical circumcision in a prospective, randomized, comparative study. The study included a total of 180 participants randomly divided into 2 unbalanced study arms: PrePex arm of 120 subjects and surgical circumcision arm of 60 subjects. The study period per subject was 9 weeks.
  The primary objective of the study was to assess the total operative time of the PrePex Device circumcision procedure versus the total operative time of surgical circumcision procedure, as defined in the Framework for Clinical Evaluation of Devices for Adult Male Circumcision (February 2011). Additionally, a number of secondary objectives were evaluated amongst them were: clinical adverse event rates, procedure preparation time and time to complete healing.
  All PrePex Device procedures were performed by experienced operators who participated in the first study. The procedures were carried out in a clean environment in a minor surgery room. The procedure was bloodless, and was conducted with no anesthesia or sutures. Subjects participated in regular follow-up visits at specified intervals.
  The surgical circumcision procedure used was the dorsal slit method which was performed by a surgeon highly experienced in adult male circumcision.
  The study yielded the following results:
  - The average PrePex total procedure time of 3 minutes and 11 seconds is much shorter than the surgical circumcision (15 min. and 33 sec.).
  - There were NO related AEs in the PrePex study arm compared to 7 related mild AEs in the surgical arm.
  - There were 3 mild un-related AEs and 1 moderate un-related AE in the PrePex arm and 1 moderate un-related AE in the surgical arm.
  - The average procedure preparation time was 3min and 24 sec for the PrePex procedure compared to 8 min and 50 sec for the surgical procedure.
  - Average time to complete healing was 38 days post PrePex device removal and 30 days post surgery.

Adverse Events

In the clinical studies there were no serious adverse events related to the PrePex device or the PrePex procedure.
In the first study, subjects reported minimal pain at all steps in the process except device removal. During device removal subjects experienced moderate pain, therefore, after the first 20 subjects, a 1-g dose of oral analgesia approximately 30 minutes before device placement and before device removal was administered. No additional painkiller was required in any subject.

Substantial Equivalence:

Characteristic	SmartKlamp	PrePex
Intended use	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	indicated for circumcision of adult males intended to be placed and removed by a health care professional trained in male circumcision and in use of the PrePex device
Location of use	Foreskin	Foreskin
Target population	Male newborn and adult	Male adult
Mode of operation	Blocks blood supply to the foreskin by clamping the foreskin	Blocks blood supply to the foreskin by clamping the foreskin
Mode of use	Single use	Single use
Material made	Plastic	Plastic
Accessories	Sizing device	Sizing device
Sizes	Sizes range from 10mm to 25mm of diameter	Sizes from 26mm to 36mm of diameter

Conclusion:

Circ MedTech believes that, based on the information provided in this submission, the PrePex is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Circ MedTech
% Ms. Shoshana (Shosh) Friedman
President & CEO
PushMed LLC
1914 J.N. Pease Place
CHARLOTTE NC 28262

JAN 1 0 2012

Re: K103695
Trade/Device Name: PrePex
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HFX
Dated: November 16, 2011
Received: November 23, 2011

Dear Ms. Friedman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D., Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103695

Device Name: PrePex

Indications for Use:

PrePex is indicated for circumcision of adult males. Prepex is intended to be placed and removed by a health care professional trained in male circumcision and in use of the PrePex device.

Prescription Use X OR Over the Counter Use____
(Per 21 CFR 801.109)

(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, Gastro-Renal, and Urological Devices
510(k) Number K103695