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AUG 3 2012

510(k) Summary for the Wuhu Snnda Medical Treatment Appliance Technology Co., Ltd.
ShangRing™

(per 21CFR 807.92 and *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*)

1. SUBMITTER/510(K) HOLDER

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Date Prepared: June 15, 2012

2. DEVICE NAME

Trade Name:	ShangRing™
Common Name:	Circumcision clamp
Classification Name:	Obstetric-Gynecologic Specialized Manual Instrument, Clamp, Circumcision, 21 CFR 884.4530
Device Class:	Class II
Classification Panel:	Obstetrical and Gynecological Panel
Product Code:	HFX

3. PREDICATE DEVICES

- Plastibell (Hollister, pre-amendment device)
- Gomco Circumcision Clamp (Thomas Medical Inc., K926353) Typo (K926535)
- Smart Klamp® (Emergo Group, Inc., K032091)

4. DEVICE DESCRIPTION

The ShangRing is a sterile, single use, disposable circumcision device consisting of two concentric rings made from polycarbonate. The outer ring is formed from two semi-circular halves that are joined together on one end by a hinge, and by interlocking ratchets on the opposite end. The inner ring is lined with a soft silicone band.

The ShangRing is available in 14 sizes with inner ring diameters ranging from 26mm to 40mm. A disposable sizing guide is provided to assist in selecting the appropriate size ShangRing.

The ShangRing is designed to perform a circumferential crushing of the foreskin (prepuce) between the inner ring and outer ring. The inner ring is placed over the penis, at the level of the coronal sulcus. After local anesthesia, the healthcare practitioner everts the patient's foreskin over the inner ring and the outer ring halves are locked together, sandwiching the foreskin between the two rings which effectively prevents bleeding. Skin forward of the crush line is trimmed away.

After the procedure, the ShangRing device remains on the patient for 7 days. After 7 days, the ShangRing is removed by the healthcare practitioner.

5. INDICATION FOR USE/INTENDED USE

The ShangRing device is indicated for circumcision of adult males, defined as circumferential excision of the foreskin or prepuce at or near the level of the coronal sulcus.

6. TECHNOLOGICAL CHARACTERISTICS

The ShangRing and the predicate devices Plastibell, Gomco, and Smart Klamp all achieve circumcision by isolating the foreskin and applying pressure to form a crush line.

The ShangRing and the Smart Klamp are both constructed from plastic and are designed for the healthcare practitioner to position the foreskin over one component and engage a locking mechanism on a companion component. When the lock is engaged, the foreskin is crushed between plastic components.

The overall design of the predicate Plastibell and Gomco devices is similar. However, for both the Plastibell and Gomco, the foreskin is everted over a bell-shaped component (plastic for Plastibell, stainless steel for Gomco). With the Plastibell device, crushing is accomplished by a piece of string. With the Gomco device, a stainless steel clamp is applied.

7. NON-CLINICAL TESTING

Wuhu Snnda conducted mechanical testing of the ShangRing to (1) determine the force required to pull apart the ShangRing's locking mechanism and (2) measure the force required to pull skin out of the ShangRing when it is in the locked position.

These tests were conducted to supplement the clinical data collected to demonstrate that while the patient is wearing the ShangRing for the indicated period of time, when exposed to the forces anticipated during normal use conditions, the outer ring will not disengage and that the device will remain in place on the patient.

Finished, sterilized ShangRing devices were tested for biocompatibility according to ISO 10993-1 for a surface device in prolonged contact with intact skin. The results confirm that the ShangRing is biocompatible for its intended use.

8. Clinical Testing

The ShangRing has been the subjective of extensive clinical evaluations, both in China and Kenya. Approximately 3000 cases in these two countries have been reported in clinical literature. These studies have demonstrated that the ShangRing is easily applied in a short surgical procedure with no suturing required. Adverse events were infrequent, and mild – requiring minimal management. Complication rates were lower than experienced with conventional methods. The clinical data collected confirms that the ShangRing is a safe and effective means of performing circumcision on adult males.

9. Conclusions Drawn from Non-clinical and Clinical Tests

The ShangRing has the same intended use and similar technological characteristics as the predicate devices. Both the ShangRing and predicate devices achieve circumcision by performing circumferential crushing of the foreskin. Non-clinical testing demonstrates that the ShangRing is biocompatible and possesses the required mechanical strength to prevent bleeding and remain attached to the foreskin for at least 7 days following closure of the locking ring. Clinical studies have demonstrated that the ShangRing is safe and effective for circumcision in the target population.

The data collected confirms that the differences in the design between the ShangRing and the predicate devices do not raise any new issues of safety and effectiveness. The information and data collected support a claim of substantial equivalence of the ShangRing to the specified predicate devices.

Table 5-1. Side-by-Side Comparison of the ShangRing with Predicate Devices

	ShangRing	Hollister Plastibell	Thomas Medical Inc. Gomco Circumcision Clamp	Emergo Group, Inc. Smart Klamp®
Regulatory Status	**Proposed**	**Pre-amendment device**	**K926535**	**K032091**
Intended Use	The ShangRing™ device is indicated for circumcision of adult males, defined as circumferential excision of the foreskin or prepuce at or near the level of the coronal sulcus.	The plastic bell with handle and string is used to tie off the foreskin or prepuce to stop blood flow such that the excess foreskin forward of the string can be cut off with minimal bleeding.	This clamp is used to hold the foreskin of the penis in place while it is being cut during a circumcision procedure.	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 the coronal sulcus, with minimal amount of preputial skin remaining.
Patient population	Adult males	Newborns to adults	Newborns to adults	Newborns to older males
Mechanism of Action	Circumferential crushing of the foreskin (i.e., crush the preputial skin between the outer plastic ring and inner plastic ring)	Circumferential crushing of the foreskin	Circumferential crushing of the foreskin (i.e., crush the preputial skin around the rim of the Gomco bell and an appropriate sized hole in the base plate)	Circumferential crushing of the foreskin (i.e., crush the foreskin between the inner tube and outer clamp)
Sizes	14 sizes (2.6, 2.8, 2.9, 3.0, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4.0 cm)	6 sizes (1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7 cm)	8 sizes (1.1, 1.3, 1.6, 2.1, 2.6, 2.9, 3.2, 3.5 cm)	4 sizes (1.0, 1.3, 1.6, 2.1 cm)
Material(s)	Inner and outer rings: Lexan (polycarbonate) Soft lining surrounding inner ring: Silicone	Bell: Plastic String: suture	Stainless steel	Cylinder: transparent polycarbonate Outer clamp: nylon
Dorsal incision	Yes, in cases when foreskin is too tight to evert. This may occur in patients without phimosis.	Yes	Yes	No
Need for suture	No	No	No	No
Additional instruments needed	Clamp, blunt end scissors, surgical scissors, 1/8" or 3 mm flat bladed screwdriver	Clamp, surgical scissors	Clamp, Cold knife	Clamp, scissors
Device remains on the patient after procedure	Yes, removed after 7 days	Yes, falls off in 3-7 days*	No	Yes, removed after 5 days**
Singe Use	Yes	Yes	No	Yes
Provided Sterile	Yes	Yes	No	Yes
Biocompatibility Established	Yes	Information not available	Information not available	Information not available

* http://www.circlist.com/instrstechs/plastibell.html
**http://smartcircumcision.com/smartklamp_2.html

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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AUG 3 2012

Re: K121789
Trade/Device Name: ShangRing™
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HFX
Dated: June 15, 2012
Received: June 19, 2012

Dear Dr. Nolte:

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

K121789

Indications for Use

510(k) Number (if known): K121789

Device Name: ShangRing™

Indications for Use:

The ShangRing™ device is indicated for circumcision of adult males, defined as circumferential excision of the foreskin or prepuce at or near the level of the coronal sulcus.

Prescription Use _x_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121789