DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 20, 2015

Medicfit Technology Sdn Bhd
% Jigar Shah
Consultant
MDI Consultants, Inc.
55 Northern Blvd
Great Neck, NY 11021

Re: K142163
Trade/Device Name: Male Circumcision Kits: RapideClamp™
Regulation Number: 21 CFR § 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HFX
Dated: March 17, 2015
Received: March 19, 2015

Dear Jigar Shah,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Herbert P. Lerner -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142163

Device Name
Male Circumcision Kits: RAPIDECLAMP

Indications for Use *(Describe)*
Circumcision of foreskin of males from infant to adult by circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus, with minimal amount of preputial skin remaining.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

MEDICFIT TECHNOLOGY SDN BHD
Male Circumcision Kits: RAPIDECLAMP™

Date Prepared: April 17, 2015

Submitted by: MEDICFIT TECHNOLOGY SDN BHD

No31, Jalan Emas 31, Bandar Sungai Emas,
42700 Banting, Selangor Darul Ehsan,
Malaysia

Establishment Number: N/A

Representative: mdi Consultants, Inc.

Proprietary Name: Male Circumcision Kits: RAPIDECLAMP™

Common Name: Male Circumcision Clamp

Classification Name: Clamp, Circumcision, Obstetrics & Gynecology
21 CFR § 884.4530

Product Code: HFX

Predicate Devices:

Trade/Proprietary Name	Manufacturer	510(k) Number
Smart Klamp®	Emergo Group Inc.	K032091
Shang Ring™	Wuhu Snnda Medical Treatment Appliance Technology Co., Ltd	K121789

Device Description:

The Male Circumcision Kits: RAPIDECLAMP™ is a surgical procedure purposely for circumcision which using a set of clamps that involves partial or complete removal of the foreskin (prepuce) of the penis. This device was designed technologically using molding process to replace the conventional method.

It was designed specifically to promote faster circumcision process, prevent severe bleeding with less pain. It contains a set of clamp with a protective shield, RAPIDECLAMP™ measuring plate, and a blade or scissor. This device known as RAPIDECLAMP™ is made up of Polycarbonate (PC) and Acrylonitrile butadiene styrene (ABS).

Generally, RAPIDECLAMP™ consists of Guide Ring, Spike Body-Front and Rear, Anti-Slip Ring, Locking Cover, and Protective Shield.

Model Numbers and Description:

RC50308 – Male Circumcision Kits: RAPIDECLAMP™
Size: 8mm
Patients: Infant to children

RC50311 – Male Circumcision Kits: RAPIDECLAMP™
Size: 11mm
Patients: Infant to children

RC50314 – Male Circumcision Kits: RAPIDECLAMP™
Size: 14mm
Patients: Infant to children

RC50317 – Male Circumcision Kits: RAPIDECLAMP™
Size: 17mm
Patients: Teenagers to adult

RC50320 – Male Circumcision Kits: RAPIDECLAMP™
Size: 20mm
Patients: Teenagers to adult

RC50323 – Male Circumcision Kits: RAPIDECLAMP™
Size: 23mm
Patients: Teenagers to adult

RC50326 – Male Circumcision Kits: RAPIDECLAMP™
Size: 26mm
Patients: Teenagers to adult

RC50329 – Male Circumcision Kits: RAPIDECLAMP™
Size: 29mm
Patients: Teenagers to adult

Indication For Use:

Circumcision of foreskin of males from infant to adult by circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus, with minimal amount of preputial skin remaining.

Technological Characteristics Compared To Predicate Device:

Characteristic	Predicate (K032091)	Predicate (K121789)	Applicant
Intended Use	The device is indicated for circumcision of newborns and older mates, 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.	The ShangRing device is indicated for circumcision of adult males, defined as circumferential excision of the foreskin or prepuce at Of near the level or the coronal sulcus.	Circumcision of foreskin of males from infant to adult by circumferential excision of the foreskin or prepuce at or near the level of coronal sulcus, with minimal amount of preputial skin remaining.
Clamping method	Clamp on the foreskin to prevent severe bleeding	Same	Same
Patient population	Newborn to adult males	Adult males	Infant to adult males
Size	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, and 4.0 cm)	4 sizes (1.0, 1.3, 1.6 and 2.1cm)	8 sizes (8, 11, 14, 17, 20, 23, 26, 29mm)
Materials	Cylinder: transparent polycarbonate Outer clamp: nylon	Inner and outer rings: Polycarbonate Soft lining of surrounding	Guide ring, Spike Body, Anti-Slip Ring, Protective Shield: Polycarbonate

		inner ring: Silicone	Locking Cover: ABS
Sterilization	Sterile	Sterile	Sterile
Single use	Yes	Yes	Yes
Need for suture	No	No	No
Removal of clamp	Remove by doctor	Remove by doctor	1. Automatically drop off after healed. 2. Using doctor. The doctor must break the safety locks on the Guide Ring (A) with pliers, unscrew the Locking Cover (D), remove the Anti-Slip Ring, cut of gangreneous tissue, remove Spike Body (B1) and removed the Guide Ring (A)
Biocompatibility	Compliant with ISO 10993	Same	Same
Mechanism of Action	The device is clamped on the foreskin to prevent blood flow into prepuce	Same	Same
Dorsal Incision	The excess foreskin is incised using medical blade or scissor	The excess foreskin is incised using medical blade or scissor	The excess foreskin is incised using medical blade or scissor
Additional Instrument	No any additional instrument. Only a set of Smartklamp, Size O-meter, medical scissors or blade	No any additional instrument. Only a set of Shangring, Special measuring tape, medical scissors or blade	No any additional instrument. Only a set of RAPIDECLAMP™, measuring plate and medical scissors or blade.

Summary of Non-clinical Testing:

MEDICFIT TECHNOLOGY has conducted mechanical testing: Locking Test to determine a known force required to confirm that the circumcision clamp is secured properly during the use. The force and break tests were also performed on the RAPIDECLAMP.
This test was conducted to supplement the clinical data collected to demonstrate the safety and effectiveness of the RAPIDECLAMP.

All materials used in the RAPIDECLAMP have been evaluated according to tests outlined in ISO 10993-1 and meet the requirements of Bluebook Memo, General Program Memorandum G95-1 biocompatibility testing for cytotoxicity, sensitization, and irritation. The materials used are Acrylonitrile Butadiene Styrene (ABS) and Polycarbonate (PC)

Summary of Clinical Testing:

Clinical test were conducted in Malaysia at following clinics/ Hospitals:

a) Ar-Raudhah Clinic
b) JB Specialist

These studies have demonstrated that the RAPIDECLAMP is easily applied in a short surgical procedure with no suturing required. The clinical data collected confirms that the RAPIDECLAMP is a safe and effective means of performing circumcision on adult males.

Conclusions Drawn From Non-Clinical And Clinical Tests:

The results of the non-clinical and clinical tests show that RAPIDECLAMP meets all safety requirements, and is substantially equivalent in clamping method, sterility, single use, no use of suture and intended use to the predicate devices.

The data collected confirms that the differences in the design between the RAPIDECLAMP 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 RAPIDECLAMP to the specified predicate devices.