February 2, 2023

wee MEDICAL
% Grace Powers, MS, MBA, RAC
Founder/ Principal Consultant
Grace Powers - Powers Regulatory Consulting
2451 Cumberland Parkway SE, Suite 3740
Atlanta, GA 30339

Re: K221356
Trade/Device Name: wee BELL Circumcision Device
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: HFX
Dated: January 6, 2023
Received: January 6, 2023

Dear Grace Powers:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221356

Device Name
wee BELL Circumcision Device

Indications for Use *(Describe)*
The wee BELL is a newborn and infant circumcision device. It is used on males with intact foreskin for the purpose of performing a circumcision (removal of the foreskin/prepuce). It consists of two components: wee Bell Circumcision device and ligature. The ligature is intended for use with the wee Bell Circumcision device only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the wee BELL Circumcision Device Traditional 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: wee MEDICAL
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Sponsor Contact: D. Preston Smith

Submission Contact: Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
Tel: 404-931-8730

Submission Date: January 25, 2023

Subject Device:

Trade Name:	wee BELL Circumcision Device
Classification Regulation:	21 CFR §884.4530
Regulation Name:	Obstetric-Gynecologic Specialized Manual Instrument
Class:	2
Common Name: Panel:	Clamp, Circumcision Obstetrics/Gynecology
Product Code:	HFX

Predicate Device: Legally marketed device to which substantial equivalence is claimed:
Circumplast circumcision device (K151095)

Device Description

The wee BELL is a newborn and infant circumcision device. It is used on males with intact foreskin for the purpose of performing a circumcision (removal of the foreskin/prepuce). It consists of two components: wee Bell Circumcision device and ligature. The ligature is intended for use with the wee Bell Circumcision device only. The wee Bell is designed to assist in the performance of a circumferential crushing of the foreskin (prepuce) by tightening the ligature around the bell portion of the device. The remaining foreskin is then removed.

The wee Bell is comprised of two components: a transparent plastic bell and a ligature. It is available in six (6) sizes to accommodate anatomy variation in the size of newborn and infant glands. The device is EtO sterilized and is a single-use device.

Figure 1: wee BELL Circumcision Device

Indications for Use

The wee BELL is a newborn and infant circumcision device. It is used on males with intact foreskin for the purpose of performing a circumcision (removal of the foreskin/prepuce). It consists of two components: wee Bell Circumcision device and ligature. The ligature is intended for use with the wee Bell Circumcision device only.

Technological Characteristics

The wee BELL Circumcision Device has similar technological characteristics as the predicate device, Circumplast Circumcision Device cleared via K151095. The intended use of the subject and predicate device are the same- the devices are intended to perform circumcisions on infant males.

Device Comparison	Subject Device: wee BELL	Predicate Device: Circumplast (K151095)
Name	Wee BELL Circumcision Device	Circumplast
Manufacturer	Wee MEDICAL, LLC	Novadien Healthcare
FDA Product Code	HFX, circumcision clamp	HFX, circumcision clamp
Regulation Name	Obstetric- gynecologic specialized manual instrument	Obstetric- gynecologic specialized manual instrument
Intended Use/ Indications for Use	The wee BELL is a newborn and infant circumcision device. It is used on males with intact foreskin for the purpose of performing a circumcision (removal of the foreskin/prepuce). It consists of two components: wee Bell Circumcision device and ligature. The ligature is intended for use with the wee Bell Circumcision device only.	The Circumplast single use circumcision device is intended to be used to perform circumcisions on infant males. This device consists of two components: Circumplast Circumcision Device and Ligature. The Ligature was tested for use with Circumplast Circumcision Device only.
Principle of Operation	Circumferential crushing of the foreskin (i.e. crush the foreskin between the inner tube and outer clamp)	Circumferential crushing of the foreskin (i.e. crush the foreskin between the inner tube and outer clamp)

Device Comparison	Subject Device: wee BELL	Predicate Device: Circumplast (K151095)
Device remains on the patient after procedure	Yes, falls off in 3 – 8 days	Yes, falls off in 3 – 7 days
Sizes	6 sizes (1.0, 1.1, 1.2, 1.3, 1.4, 1.5cm)	4 sizes (0.95, 1.1, 1.2, 1.3 cm)
Materials	Bell: Plastic Ligature: linen	Bell: plastic Ligature: linen
Device Colorant	No colorant	Unknown
Condition of Use	Single Use	Single Use
Sterilization Method	EtO	EtO
Shelf Life	18 months	Unknown

Performance Data

Nonclinical functional performance testing was performed on the subject device and included functional testing (visual inspection, tensile testing, hoop stress testing and smoothness testing), packaging testing per ASTM F88-21, ASTM D4169-22 and ISO 11607, sterilization validation per ISO 11135:2014 and biocompatibility according to ISO 10993-1 for a surface device in prolonged contact with intact skin. Additionally, material mediated pyrogenicity was conducted.

Conclusion

The wee BELL Circumcision Device is substantially equivalent to the legally marketed predicate device as demonstrated by the similar indications for use, similar technologies and performance data, and does not raise different questions of safety and effectiveness.