November 18, 2022

Medline Industries, Inc.
Jennifer Mason
Regulatory Affairs Principal
Three Lakes Drive
Northfield, IL 60093

Re: K212911
Trade/Device Name: Konig Mogen Clamp
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: HFX
Dated: October 7, 2022
Received: October 11, 2022

Dear Jennifer Mason:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212911

Device Name
Konig Mogen Clamp

Indications for Use *(Describe)*
The Konig Mogen Clamp is an instrument used in a medical procedure to compress the foreskin of the penis during the circumcision of a male infant or child 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.

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

Contact Person
Jenny Ly
Regulatory Affairs Specialist
Phone: 224-234-7457
Email: jly@medline.com

Summary Preparation Date
September 10, 2021

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Konig Mogen Clamp
Proprietary Name: Konig Mogen Clamp
Common Name: Circumcision Clamp
Classification Name: Clamp, Circumcision
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Product Code: HFX
Classification Panel: Obstetrics/Gynecology
Regulatory Class: Class II
Regulation #: 21 CFR 884.4530

Predicate Device
Medicon Mogen Circumcision Clamp
K100916

Device Description
The Konig Mogen Clamp is an instrument used in a medical procedure to compress the foreskin of the penis during the circumcision of a male infant or child only.

The Konig Mogen Clamp consists of an arm with a locking mechanism in order facilitate compression on the foreskin. The locking mechanism consists of a lock connected to a lock bar using a pin. The clamp is fixed with a spot welding point, which allows for a maximum opening of 2.5 mm. The edges of the closing area are chamfered and rounded to avoid tissue injury.

The Konig Mogen Clamp is a reusable instrument that is provided non-sterile to be sterilized by the user. The Konig Mogen Clamp will be validated for use in pre-vacuum steam sterilization.

Indications for Use

The Konig Mogen Clamp is an instrument used in a medical procedure to compress the foreskin of the penis during the circumcision of a male infant or child only.

The Konig Mogen Clamp is intended for use in healthcare facilities, including hospitals, medical clinics and surgical centers, by surgeons of proper training and experience.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Konig Mogen Clamp	Medicon Mogen Circumcision Clamp	Different
510(k) Reference	N/A	K100916	Different
Product Owner	Medline Industries, Inc.	Medicon	Different
Product Code	HFX	HFX	Same
Intended Use	The Konig Mogen Clamp is an instrument used in a medical procedure to compress the foreskin of the penis during circumcision of a male infant or child.	The Mogen Circumcision Clamp is an instrument used in a medical procedure to compress the foreskin of the penis during circumcision of a male infant or child.	Same
Regulation Number	21 CFR 884.4530	21 CFR 884.4530	Same
Design Features	Clamp and locking bar	Clamp and locking bar	Same
Design Configurations	In the open position, the jaws are designed to separate to a maximum of 2.5 mm. For safe clamping	In the open position, the jaws are designed to separate to a maximum of 2.5 mm. For safe clamping the Medicon	Same

	the Konig Mogen Clamp is locked with a defined closing force. For safety reasons, the lock screw of the clamp is fixed with a spot welding point in order not to become loose.	Mogen Clamp is locked with a defined closing force. For safety reasons, the lock screw of the clamp is fixed with a spot welding point in order not to become loose.	
Materials	Stainless Steel – corrosion resistant	Stainless Steel– corrosion resistant	Same
Performance Specifications	Standards ASTM F 899-09 and ISO 7153-1 Standard Specification for Stainless Steels for Surgical Instruments ASTM E322-12 Standard Test Method For Analysis Of Low-Alloy Steels And Cast Irons By Wavelength Dispersive X-Ray Fluorescence Spectrometry ASTM F1089-10 Standard Test Method for Corrosion of Surgical Instruments ASTM E18 - 20 Standard Test Methods for Rockwell Hardness of Metallic Materials	Standards ASTM F 899-09 and ISO 7153-1 Standard Specification for Stainless Steels for Surgical Instruments ASTM F 1089-10 and ISO 13402 Standard Specifications for resistance against corrosion and autoclaving of Surgical Instruments.	Different
Prescription vs. OTC	Prescription	Prescription	Same
Contact Durations	Surface Device Breached or compromised surface Limited duration	Surface Device Breached or compromised surface Limited duration	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Single Use vs. Reusable	Reusable	Reusable	Same
Sterilization Method	Steam sterilization	Steam sterilization	Same

Summary of Non-Clinical Testing

Biocompatibility, cleaning and sterilization, performance, and physical properties testing was conducted on the Konig Mogen Clamp to demonstrate that the product meets its intended use.

Study	Description	Results
Biocompatibility	ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity ISO 10993-17:2002 Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	The Konig Mogen Clamp was non-toxic.
Cleaning and Sterilization Testing	ISO 17665-1:2006 Moist Heat – Req. for the development, validation, and routine control of a sterilization process for medical devices. ISO 15883-2:2006 Req. and tests for washer-disinfectors employing thermal disinfection for surgical instruments (Used for the cleaning and thermal disinfection for reusable surgical instruments) ANSI/AAMI ST79: 2017 Guide to steam sterilization and sterility assurance in health care facilities	No growth at the end of the incubation period.
Performance Testing	Custom Grip Test ASTM E322-12 Standard Test Method For Analysis Of Low-Alloy Steels And Cast Irons By Wavelength Dispersive X-Ray Fluorescence Spectrometry ASTM F1089-10 Standard Test Method for Corrosion of Surgical Instruments ASTM E18 - 20 Standard Test Methods for Rockwell Hardness of Metallic Materials	Test articles met the acceptance criteria.

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Konig Mogen Clamps are as safe and as effective for their intended use as the predicate device, Medicon Mogen Circumcision Clamp, under K100916.