



February 25, 2026

Medline Industries, LP
Jennifer Mason
Regulatory Affairs Principal
Three Lakes Dr.
Nortfield, Illinois 60093

Re: K251687
Trade/Device Name: Konig Bell Circumcision Clamp
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HFX
Dated: May 30, 2025
Received: January 5, 2026

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251687

?

Please provide the device trade name(s).

?

Konig Bell Circumcision Clamp

Please provide your Indications for Use below.

?

The Konig Bell Circumcision clamps are reusable instruments used in a procedure to compress the foreskin of the penis during the circumcision of male infant or child. Use of the Konig Bell Circumcision clamps in adults is to assist in Human Immunodeficiency Virus (HIV) prevention.

Please select the types of uses (select one or both, as applicable).

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

?



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Northfield, IL 60093

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510(k) SUMMARY

[AS REQUIRED BY 21 CFR 807.92(c)]

Submitter / 510(k) Sponsor

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person

Contact Person: Jennifer Mason, Regulatory Affairs Principal
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date

February 11, 2025

Type of 510(k) Submission

Traditional

Device Name / Classification

Trade Name: Konig Bell Circumcision Clamp
Common Name: Clamp, Circumcision
Classification Name: Obstetric-gynecologic specialized manual instrument
Product Code: HFX
Classification Panel: Obstetrics/Gynecology
Regulatory Class: Class II
Regulation Number: 21 CFR 884.4530

Predicate Device

Fine Surgical Circumcision Clamp
K040052

Device Description

The Konig Bell Circumcision Clamp is intended to be used in a medical procedure to compress the foreskin of the penis during circumcision of a male infant, child or adult. The device is manufactured from German-grade 304 stainless steel and is composed of four parts: base, bell, hook arm and thumb screw. The device



is offered in the following bell sizes 0.8cm, 1.1cm, 1.3cm, 1.45cm, 1.6cm, 2.1cm, 2.6cm, 2.9cm, 3.2cm and 3.5cm.

The Konig Bell Circumcision Clamp is packaged in a low-density polyethylene film pouch. The device is provided non-sterile and is intended to be cleaned and sterilized at the healthcare facility prior to use. Validated cleaning and steam sterilization instructions are included in the instructions for use.

Indications for Use

The Konig Bell Circumcision clamps are reusable instruments used in a medical procedure to compress the foreskin of the penis during the circumcision of male infant or child. Use of the Konig Bell Circumcision clamps in adults is to assist in Human Immunodeficiency Virus (HIV) prevention.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Konig Bell Circumcision Clamp	Fine Surgical Circumcision Clamp	Different
510(k) Reference	N/A	K040052	N/A
Product Owner	Medline Industries, LP	Fine Surgical Instruments, Inc.	Different
Product Code	HFX	HFX	Same
Intended Use	A circumcision clamp is an instrument used in a medical procedure to compress the foreskin of the penis during circumcision of male infant or child. Use of the Konig Bell Circumcision clamps in adults is to assist in HIV prevention.	A circumcision clamp is an instrument used in a procedure to compress the foreskin of the penis during circumcision of male infant or child.	Similar
Regulation Number	21 CFR 884.4530	21 CFR 884.4530	Same
Design Features	Base Plate Arm Bell Screw	Base Plate Arm Bell Screw	Same
Design Configurations	0.8cm 1.1cm 1.45cm 1.6cm 2.1cm	1.1cm 1.3cm 1.45cm 1.6cm	Different



	2.6cm 2.9cm 3.2cm 3.5cm		
Materials	Stainless Steel 304	Chrome plated brass	Different
Prescription vs. OTC	Prescription	Prescription	Same
Single Use vs. Reusable	Reusable	Single use	Different
Sterility	Non-sterile intended to be sterilized prior to use	Non-sterile intended to be sterilized prior to use	Same
Sterilization Method	Pre-vacuum Steam sterilization	Unable to determine	Unable to determine

Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for the Konig Bell Circumcision Clamp was conducted in accordance with ISO 10993-1:2009 *Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process*, and FDA guidance document, *Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” September 2023*. The Konig Bell Circumcision Clamp is classified as a surface device in contact with breached or compromised surface for a limited contact duration of less than 24 hours. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2009 Annex A.

The following tests were performed to evaluate the biocompatibility of the Konig Bell Circumcision Clamp:

- Cytotoxicity – ISO 10993-5: Tests for Cytotoxicity – *In Vitro* methods
- Sensitization – ISO 10993-10: Tests for Sensitization
- Irritation – ISO 10993-10: Tests for Irritation
- Material Mediated Pyrogenicity – ISO 10993-11: Tests for Systemic Toxicity
- Acute Toxicity – ISO 10993-11: Tests for Systemic Toxicity

A description of the sample article used for biocompatibility testing, a biological evaluation and complete biocompatibility test reports are located in the eSTAR submission.

Performance Testing (Bench)

The following performance testing was conducted on the Konig Bell Circumcision Clamp.



Dimensional Analysis

Measurements were taken of both the smallest and the largest Konig Bell Circumcision Clamps to ensure that the devices meet the specifications on the engineering drawings. A total of thirteen samples of both the smallest and largest bell sizes were used. All thirteen samples of both sized clamps met the acceptance criteria for dimensions.

Grip Testing

Comparison grip testing was performed on the predicate, Fine Surgical Circumcision Clamp and the Konig Bell Circumcision Clamp. To simulate use with actual foreskin, a latex substrate was loaded into the circumcision clamps and pulled vertically above and below the clamp with approximately 10N of force. The latex substrate was then inspected for slippage from the clamp and any signs of cuts, tears, or visible damage. Both the predicate and the subject devices met the acceptance criteria for grip strength.

Corrosion Testing

Corrosion testing using the boil test per ASTM F1089-18 was performed on thirteen samples of the Konig Bell Circumcision Clamp. The instruments were thoroughly cleaned using an ultrasonic cleaner and then boiled in a glass container with distilled water for 30 minutes. After 30 minutes the circumcision clamps were removed and allowed to air dry for 2 hours. After drying, the instruments were inspected for any rust formation. All thirteen samples successfully met the acceptance criteria and did not show any signs of corrosion.

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

Clinical literature reference

Millard PS, Wilson HR, Goldstuck ND, Anaso C. Rapid, minimally invasive adult voluntary male circumcision: a randomised trial of Unicirc, a novel disposable device. S Afr Med J. 2013;104(1):52-57. doi:10.7196/samj.7357

Other Testing

Summary of Clinical Testing

Not applicable.



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Conclusion

In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, Medline Industries, LP. concludes that the Konig Bell Circumcision Clamp is as safe and as effective for their intended use as the predicate device, Fine Surgical Circumcision Clamp (K040052).