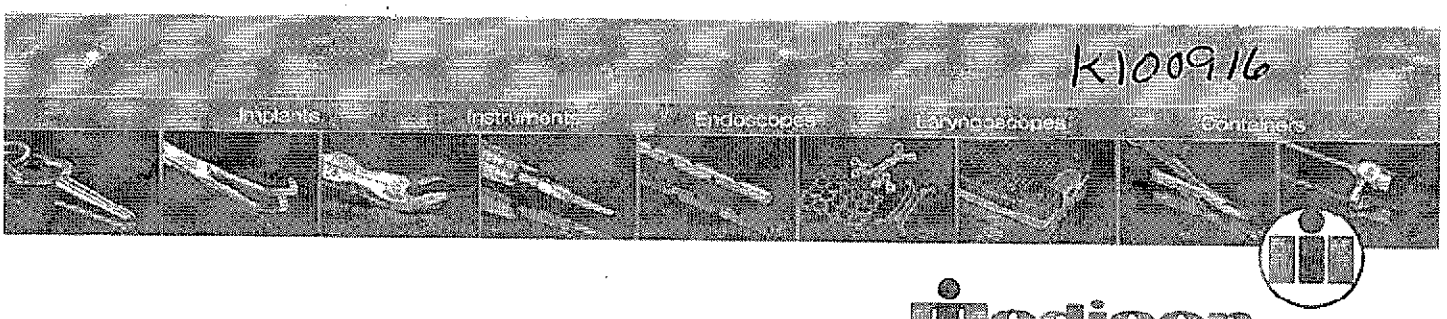


K100916

MEDICON eG * Postfach 44 55 * D-78509 Tuttlingen

Medicon Instrumente
the art of surgery

MEDICON eG, Chirurgiemechaniker-Genossenschaft
Gänsäcker 15, D-78532 Tuttlingen (parcel post)
Postfach 44 55, D-78509 Tuttlingen (letter post)
Germany

DEC - 6 2010

Traditional 510 (k) - HFX

2. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Medicon Mogen Circumcision Clamp

MEDICON eG
(As required by Section 807.92)

2.1 Submitter: (807.92 (a) (1))

MEDICON eG
Gaensaecker 15
D-78532 Tuttlingen
Germany

Tel. +49 7462 2009 0
Fax: +49 7462 200950
eMail: sales@medicon.de

2.2 Contact Person:

Joachim Schmid
CEO
Tel. +49 7462 2009 0

2.3 Date Summary Prepared: (807.92 (a) (1))

December 1, 2010

2.4 Device Names: (807.92 (a) (2))

Proprietary Name:	Medicon Mogen Circumcision Clamp
Common name:	Mogen Clamp, Mogen Circumcision Clamp, Medicon Mogen Clamp, Circumcision Clamp,
Classification Name:	Clamp, Circumcision
Medical Specialty:	Obstetrics/Gynecology
Product Code(s):	HFX
Regulation Number:	884.4530
Device Class:	2

2.5 Reason for Submission: (807.81(2))

New Device.

2.6 Predicate Device: (807.92(a)(3))

T. S. Medical Circumcision Clamp, K033403

2.7 Device Description:

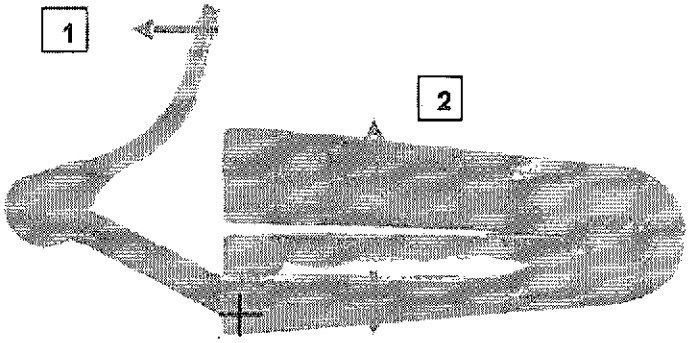
The Medicon Mogen Circumcision Clamp is a stainless steel, reusable circumcision clamp consisting out of multiple components, including clamp and locking bar. For safety reasons the lock screw of the clamp is fixed with a spot welding point in order not to become loose. For safety reasons the clamp opens to a maximum of 2.5 mm, in order not to trap the glans and the edges of closing area are chamfered and rounded inside and outside to avoid injuries

2.8 Intended Use: (807.92 (a) (5))

The Medicon 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.

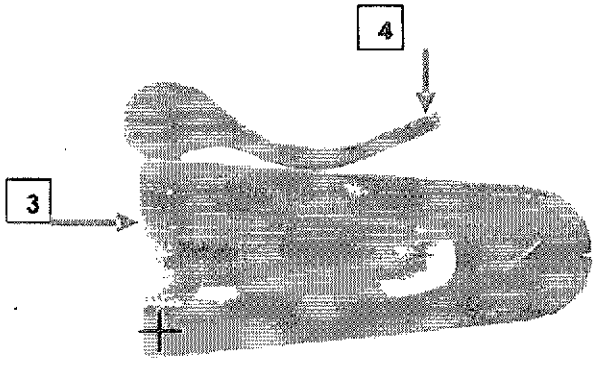
2.9 Description of Device Function:

Opening of the Medicon Mogen Circumcision Clamp:



(1) By lifting the clamping lever and turning away of flap, the clamp can be opened (2);

Closing and locking of the Medicon Mogen Circumcision Clamp:



(2) By putting the flap against the clamp, the clamp can be closed (4) and locked with the lamping lever;

2.10 Environment of Use:

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

2.11 Sterility Information:

The Medicon Mogen Circumcision Clamp is offered non-sterile for autoclave steam sterilization by user.

2.12 Comparison with SE Device: (807.92 (a) (6))

Based on the information provided in the predicate 510(k) summary, the predicate device is identical to the Medicon Mogen Circumcision Clamp in indications for use, operating principle, design and material. The Medicon Mogen Circumcision Clamp technical information, intended use and performance information, as provided in this premarket notification, shows the subject device to be as safe and effective as the current legally marketed predicate device.

2.13 Summary of physical and performance characteristics

The Medicon Mogen Circumcision Clamp is made out of stainless steel. The stainless steel used is in accordance with the standards ASTM F 899 and ISO 7153-1. All components of the clamp are corrosion resistant.

The Medicon Mogen Circumcision Clamp is supplied non-sterile but is intended to be reused. Decontamination, cleaning and moist heat sterilization has to be performed according to the general instructions described in the package insert prior to each use.

In the open position, the jaws are designed to separate to a maximum of 2.5 mm. For safe clamping the Medicon 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.

2.14 Discussion of Non-Clinical Laboratory Tests

The following Non-Clinical Testing was performed:

- Sterilization validation
- Performance testing – mechanical, material, and corrosion resistance testing

The Medicon Mogen Circumcision Clamp is identical to the Predicate Device in intended use and basic design. The materials used are the same or similar as that used to manufacture the Predicate Device. The Medicon Mogen Circumcision Clamp has been tested and complies with the Standards ASTM F 899-09 and ISO 7153-1 Standard Specification for Stainless Steels for Surgical Instruments and with ASTM F 1089-10 and ISO 13402 Standard Specifications for resistance against corrosion and autoclaving of Surgical Instruments. The test results demonstrate that mechanical performance characteristics, material properties, corrosion resistance and sterilization specifications of the device are substantially equivalence to the Predicate Device.

2.15 Discussion of Clinical Tests

Clinical Testing was not performed in order to establish substantial equivalence as this type of technology and procedure has a long history of clinical use.

2.16 Conclusions

The Medicon Mogen Circumcision Clamp is substantial equivalence to the Predicate Device and it is as safe and effective for its intended use as the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Joachim Schmid
CEO
Medicon eG
Gansacker 15
78532 Tuttlingen
GERMANY

DEC - 6 2010

Re: K100916
Trade/Device Name: Medicon Mogen Clamp
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HFX
Dated: November 8, 2010
Received: November 16, 2010

Dear Mr. Schmid:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

DEC - 6 2010

510(k) Number (if known): K100916

Device Name: Medicon Mogen Circumcision Clamp

Indications For Use:

The Medicon 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.

Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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, Abdominal and Radiological Devices
510(k) Number K100916