February 23. 2018

Sutter Medizintechnik GmbH
% Andre Kindsvater
Senior Consultant, RA/QA
Emergo Global Consulting LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K171869
Trade/Device Name: Sutter CURIS RF Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 10, 2017
Received: January 19, 2018

Dear Andre Kindsvater:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171869

Device Name
Sutter CURIS® RF Generator

Indications for Use *(Describe)*

Orthopedic, arthroscopic, spinal and neurosurgical:
For resection and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal and neurosurgical procedures.
For soft tissue resection and coagulation during arthroscopic surgical procedures of knee, shoulder, ankle, elbow, hip and wrist.

Cutting:
Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, Blepharoplasty.

Blended Cutting and Coagulation:
Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage, skin tags, papilloma Keloids, Keratosis, Verrucae, Basal cell carcinoma, Nevi, Fistulas, Epithelioma, cosmetic repairs, cysts, abscesses, development of skin flaps.

Hemostasis and nonablative Coagulation:
Control of bleeding, Epilation, Teleangiectasia.

Bipolar:
Pinpoint, Precise Coagulation, Pinpoint Hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage.

Contraindications:
This device is not intended for vessel sealing.

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
Sutter CURIS® RF Generator
K171869

1. Submission Sponsor

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Contact: André Kindsvater, Senior Consultant, RA/QA
email: project.management@emergogroup.com

3. Date Prepared

February 19th, 2018

4. Device Identification

Trade/Proprietary Name:	Sutter CURIS® RF Generator
Common/Usual Name:	RF Generator
Classification Name:	Electrosurgical, cutting & coagulation & accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General and Plastic Surgery

5. Legally Marketed Predicate Device(s)

Electrosurgical Generator Surgi-Max by Elliquence LLC; K100390

6. Indication for Use Statement

The Sutter CURIS® RF Generator is intended for:

Orthopedic, arthroscopic, spinal and neurosurgical:

For resection and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal and neurosurgical procedures

For soft tissue resection and coagulation during arthroscopic surgical procedures of knee, shoulder, ankle, elbow, hip and wrist

Cutting:

Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, Blepharoplasty

Blended Cutting and Coagulation:

Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage, skin tags, papilloma Keloids, Keratosis, Verrucae, Basal cell carcinoma, Nevi, Fistulas, Epithelioma, cosmetic repairs, cysts, abscesses, development of skin flaps

Hemostasis and nonablative Coagulation:

Control of bleeding, Epilation, Teleangiectasia

Bipolar:

Pinpoint, Precise Coagulation, Pinpoint Hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage

Contraindications:

This device is not intended for vessel sealing.

7. Device Description

The Sutter CURIS® RF Generator is a compact source of high radiofrequency RF energy to be employed for a variety of electrosurgical procedures. This is achieved by the selection of different wave forms and power levels on the front panel of the device. All selections are effected through pushbuttons and knobs. Lamps give the operator feedback on the status.

The power level for each mode is indicated by front-panel digital displays. During self-test or for error messages these digital displays also serve as indicators. Activation of output power is performed through foot switch and/or hand switch. Monopolar and bipolar electrodes are available for use.

The maximum power output of the device in CUT mode is 100 watts (at 400 Ohms load), and 80 watts maximum in COAG mode at 50 Ohms. Operating frequency of the device is maintained at 4.0 MHz.

The device offers both monopolar and bipolar output wave forms. In monopolar mode it offers two CUT wave forms and two COAG wave forms. In bipolar mode it offers three CUT wave forms and three COAG wave forms.

The Sutter CURIS® RF Generator is packaged together with power cord and instruction manual. Optional accessories are a foot switch with cable and appropriate monopolar and bipolar cables.

8. Sterilization

The Sutter CURIS® RF Generator is not distributed as a sterile device, and is not intended to be sterilized at any time.

9. Biocompatibility

The Sutter CURIS® RF Generator is a table-top device which has no contact with the patient.

10. Technological Characteristics

Table 5A – Technological Characteristics

Mains supply	100-240 V; 50/60 Hz
Power consumption without RF output	approx. 50 VA
Power consumption at max. output power	approx. 500 VA
Protection class	I
LF and RF leakage currents	according to IEC 60601-2-2
Type	CF; defibrillator safe
Weight	approx. 5.0 kg
Dimensions W x H x D	320 mm x 170 mm x 385 mm
Environmental conditions for transportation and storage: Ambient temperature Relative humidity Atmospheric pressure	 25 °C to +70 °C 10 % to 100 % 500 hPa to 1060 hPa
Environmental conditions for operation: Ambient temperature Relative humidity Atmospheric pressure	 +10 °C to +40 °C 30 % to 75 % 700 hPa to 1060 hPa

11. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Sutter CURIS® RF Generator and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, Sutter Medizintechnik GmbH completed a number of non-clinical performance tests against applicable standards.

Table 5C – Performance Standards Testing Summary

Test		Pass / fail criteria	Results
1	Electrical safety	Compliance to IEC 60601-1: 2005	Passed
2	Electrical safety	Compliance to IEC 60601-2-2:2009	Passed
3	Electromagnetic compatibility	Compliance to IEC 60601-1-2: 2007	Passed

Test		Pass / fail criteria	Results
4	Risk Management	Compliance to ISO 14971:2007	Passed
5	Software Performance	Compliance to IEC 62304:2006	Passed

To demonstrate that the Sutter CURIS® RF Generator meets all design specifications and performance requirements, nonclinical bench testing has been performed in accordance with the internal R&D process in compliance with the proposals and recommendations of FDA guidance: "Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery" – Guidance for Industry and Food and Drug Administration Staff, August 15, 2016.

In particular, tests have been planned and carried out with respect to the following subject areas:

- Mechanical safety
- Functional safety Testing
- System Performance Testing
- Thermal effects on tissue
- Usability
- Drop Tests

Mechanical safety:

Protection against mechanical hazards of ME equipment and ME systems has been tested in compliance with IEC 60601-1:2005. The testing demonstrated that all applicable requirements have been met.

Functional safety testing:

The appropriate delivery of energy from the CURIS® RF Generator to the accessory and patient is controlled by software.The functional safety concept of the CURIS® RF Generator has been tested in compliance with IEC 60601-1:2005, IEC 60601-2-2:2009 and IEC 62304:2006.

System Performance Testing:

System performance testing has been performed in accordance with the internal R&D process and in compliance with the proposals and recommendations of FDA guidance: "Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery" – Guidance for Industry and Food and Drug Administration Staff, August 15, 2016.

The review of design requirements was based on the following test methods:

Control of labeling and packaging, control of weight and external dimensions, visual inspections, functional inspections and measurements of the generator. The corresponding performance testing demonstrated that all design specifications and performance requirements have been met.

Thermal effects on tissue

The Sutter CURIS® RF Generator has been tested for thermal effects on tissue with commercially available electrosurgical accessories which are widely used and cleared for marketing in the USA. For comparison reasons the predicate device was included.

The experimental arrangement was carried out in line with FDA guidance: "Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery" –Guidance for Industry and Food and Drug Administration Staff, August 15, 2016.

In all modes, the CURIS® RF Generator delivered adequate coagulation and cutting performance. Generally, CURIS® RF Generator and the predicate device performed similarly.

Usability:

The CURIS® RF Generator has been investigated in order to show that design specifications and performance requirements are met. The results of the thermal effect performance testing, system performance testing, market acceptance tests, and user scenarios tests have been evaluated. It has been assessed that the CURIS® RF Generator fulfills the intended usability and meets the respective design input.

Drop Tests:

Drop tests with the CURIS® RF Generator in its designated packaging have been executed to demonstrate that design specifications and performance requirements are met.

Internal verification and validation testing confirms that product specifications are met which are equivalent to the predicate device in design and technological characteristics. The testing results support that the requirements for performance and electrical safety testing were met for the acceptance of the device. The CURIS® RF Generator passed all testing and supports the claims of substantial equivalence to the predicate device.

12. Substantial Equivalence Discussion

Table 5B – Comparison of Characteristics

Manufacturer	**Sutter Medizintechnik GmbH**	**Elliquence LLC**	**SIGNIFICANT DIFFERENCES**
Trade Name	**CURIS® RF Generator**	**Surgi-Max**	N/A
510(k) Number	N/A	K100390	N/A
Product Code	GEI	GEI	same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	same
Regulation Name	Electrosurgical, cutting & coagulation & accessories	Electrosurgical, cutting & coagulation & accessories	same
Intended Use	The Sutter CURIS ® RF Generator is intended for: Orthopedic, arthroscopic, spinal and neurosurgical: For resection and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal and neurosurgical procedures For soft tissue resection and coagulation during	Orthopedic, arthroscopic, spinal, and neurosurgical: For resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal and neurological procedures. For soft tissue resection and ablation during arthroscopic	similar

Manufacturer	**Sutter Medizintechnik GmbH**	**Elliquence LLC**	**SIGNIFICANT DIFFERENCES**
Trade Name	**CURIS® RF Generator**	**Surgi-Max**	N/A
	arthroscopic surgical procedures of knee, shoulder, ankle, elbow, hip and wrist. Cutting: Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, blepharoplasty Blended Cutting and Coagulation: Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, fistulas, epithelioma, cosmetic repairs, cysts, abscesses, development of skin flaps Hemostasis and nonablative Coagulation: Control of bleeding, epilation, teleangiectasia Bipolar: Pinpoint, precise coagulation, pinpoint hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective	surgical procedures of knee, shoulder, ankle, elbow, hip and wrist. Cutting: Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, blepharoplasty. Blended Cutting and Coagulation: Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, Fistulas, epithelioma, cosmetic repairs, cysts, abscesses, Development of skin flaps. Hemostasis and Nonablative Coagulation: Control of bleeding, epilation, telangiectasia Bipolar: Pinpoint, precise coagulation, pinpoint hemostasis, in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective	

Manufacturer	**Sutter Medizintechnik GmbH**	**Elliquence LLC**	**SIGNIFICANT DIFFERENCES**
Trade Name	**CURIS® RF Generator**	**Surgi-Max**	N/A
	hemorrhage control, epistaxis treatment and turbinate shrinkage Contraindications: This device is not intended for vessel sealing.	hemorrhage control, epistaxis treatment, and turbinate shrinkage	
Material	Metal & plastics	Metal & plastics	Similar- the differences do not affect safety and effectiveness
Battery Operated	no	no	same
AC Powered	yes	yes	same
Frequency	4 MHz	4 MHz / 1.71 MHz	Similar- the differences do not affect safety and effectiveness
Delivery Mode	Monopolar and bipolar	Monopolar and bipolar	same
Waveforms	Mono contact Coag: m Mono Softspray Coag: modulated Mono Cut 1: sinusoidal Mono Cut 2: modulated Bipo precise Coag: modulated Bipo macro Coag: modulated Bipo RaVoR Coag: modulated Bipo Cut1: sinusoidal Bipo Cut 2: modulated Bipo Cut Excise: modulated	Mono Hemo: modulated Mono CUT: sinusoidal Mono CUT/COAG: modulated Bipo Hemo: modulated Bipo Turbo: modulated	Similar- the differences do not affect safety and effectiveness
Electrical Safety Testing Passed	IEC 60601-1 all applicable requirements met	IEC 60601-1 all applicable requirements met	same
Electromagnetic compatibility	IEC 60601-1-2 all applicable requirements met	IEC 60601-1-2 all applicable requirements met	same

13. Statement of Substantial Equivalence

The CURIS® RF Generator device is substantially equivalent to the predicate device, and does not raise different questions regarding its safety and effectiveness as compared to the predicate device(s).