February 11, 2026

Sutter Medizintechnik GmbH
℅ Arne Briest
Managing Director
VISAMED GmbH
Kastellstr. 8
Karlsruhe, 76227
Germany

Re: K251813
Trade/Device Name: CURIS II RF Generator (REF 360100-05)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 13, 2026
Received: January 13, 2026

Dear Arne Briest:

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: 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.

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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.02.11 16:34:37 -05'00'

For
Colin Kejing Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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.	K251813

Please provide the device trade name(s).

CURIS II RF Generator (REF 360100-05)

Please provide your Indications for Use below.

The Sutter Sutter CURIS® II 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.

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)

K251813

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92 upon which substantial equivalence is based.

I SUBMISSION SPONSOR and APPLICATION CORRESPONDANT

A. SUBMISSION SPONSOR

Sutter Medizintechnik GmbH

Alfred-Walz-Str. 22
79312 Emmendingen - Germany

www.sutter-med.com

Tel +49 (0) 7641 962 56 0

Contact Person :

Simone Peschl

VP Business Development & Market Access

simone.peschl@sutter-med.de

B. APPLICATION CORRESPONDANT

VISAMED GmbH

Kastellstr. 8
D-76227 Karlsruhe-Germany

www.visamed.com

Tel +49 (0)170-4888 498

Contact Person :

Arne Briest

CEO

arne.briest@visamed.com

II. Dated prepared: February 11, 2026

III DEVICE IDENTIFICATION

Name of Device:	**Sutter CURIS® II RF Generator**
Common Name:	**Sutter CURIS® II RF Generator**
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories (21 CFR § 878.4400)
Classification Panel:	General & Plastic Surgery
Regulatory Class:	II
Product Code:	GEI
510k #:	K2518113

IV PREDICATE DEVICE

K171869 – Sutter CURIS® RF Generator

V. DEVICE DESCRIPTION

The Sutter CURIS® II 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 waveforms and power levels on the front panel of the device. All selections are activated through pushbuttons and knobs. Lamps give the operator feedback on the status.

The power level for each mode is indicated by the 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 and instruments from Sutter Medizintechnik GmbH or other manufacturers are available for use.

The maximum power output of the device in CUT mode is 120 Watt at 700 Ohm load, and 80 Watt maximum in COAG mode at 60 Ohm. Operating frequency of the device is maintained at 4.0 MHz.

Model number	Component	Description
REF 360100–05	Sutter CURIS® II RF Generator	Device including power cord and Instruction manual

VI INDICATIONS FOR USE

The Sutter CURIS® II 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, telangiectasia.

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.

VII Sterilization

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

VIII Biocompatibility

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

IX Technological Characteristics

Table 1 – 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	313 mm x 166 mm x 408 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

X Non-Clinical Performance Data

To support the demonstration of safety and effectiveness of the Sutter CURIS® RF Generator, and to establish substantial equivalence to the identified predicate device in the 510(k) submission, Sutter Medizintechnik GmbH conducted a series of non-clinical performance tests. These tests were performed in accordance with applicable FDA-recognized consensus standards and relevant guidance documents.

Table 2 – Performance Standards Testing Summary

Test		Pass / fail criteria	Results
1	Electrical safety	Compliance to IEC 60601-1	Passed
2	Electrical safety	Compliance to IEC 60601-2-2	Passed
3	Electromagnetic compatibility	Compliance to IEC 60601-1-2	Passed
4	Risk Management	Compliance to ISO 14971	Passed
5	Software Performance	Compliance to IEC 62304	Passed

To demonstrate that the Sutter CURIS® II 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.

Tests have been planned and carried out with respect to the following subject areas:

- Mechanical Safety Testing
- 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. The testing demonstrated that all applicable requirements have been met.

Functional safety testing:

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

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 CURIS® II 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.

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

Usability:

The CURIS® II RF Generator has been investigated 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® II RF Generator fulfills the intended usability and meets the respective design input.

Drop Tests:

Drop tests with the CURIS® II 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® II RF Generator passed all testing and supports the claims of substantial equivalence to the predicate device.

XI COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Sutter CURIS® RF Generator is the predicate device for the Sutter CURIS® II RF Generator.

Manufacturer	Sutter Medizintechnik GmbH		Significant Differences
Trade Name	**CURIS® II RF Generator**	**CURIS® RF Generator**	
	Subject Device	Predicate	-
510(k) Number	TBD	**K171869**	-
Product Code	GEI	GEI	identical
Regulation Number	878.4400	878.4400	identical
Class	2	2	identical
Regulation Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	identical
Indications for Use	The Sutter Sutter CURIS® II 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.	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 ablation 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.	identical

Manufacturer	Sutter Medizintechnik GmbH		Significant Differences
Trade Name	**CURIS® II RF Generator**	**CURIS® RF Generator**	
	Subject Device	Predicate	-
	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.	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.	
Material	Metal & plastics	Metal & plastics	Similar - the differences do not affect safety and effectiveness
Sterile	no	no	identical
Single Use	no	no	identical
Overall Design	PEMS and software	PEMS and software	same

Manufacturer	Sutter Medizintechnik GmbH		Significant Differences
Trade Name	**CURIS® II RF Generator**	**CURIS® RF Generator**	
	Subject Device	Predicate	-
Dimensions (width x height x depth) in mm	313 mm x 166 mm x 408 mm	320 mm x 170 mm x 385 mm	Similar - the differences do not affect safety and effectiveness
Delivery Mode	Monopolar and Bipolar	Monopolar and Bipolar	identical
Mains Connection/ AC Powered	100 -240 V, 50/60 Hz	100 -240 V, 50/60 Hz	identical
Power consumption	Without RF output: Approximately 50 VA At max. output power: Approximately 500 VA	Without RF output: Approximately 50 VA At max. output power: Approximately 500 VA	identical
Battery Operated	no	no	identical
Light Source	no	no	identical
Nominal Frequency	4.00 MHz for all modes	4.00 MHz for all modes	identical
Output Power Limit	40 – 120 Watt	40 – 100 Watt	Similar- the differences do not affect safety and effectiveness
Operating Modes - Monopolar	**CUTTING - CUT 1** max power: 120 Watt @ 700 Ohm max current: 1,1 A Modulation (MOD): no	**CUTTING - CUT 1** max power: 100 Watt @ 600 Ohm max current: 1,1 A Modulation (MOD): no	Similar - the differences do not affect safety and effectiveness
	CUTTING - CUT 2 max power: 90 Watt @ 700 Ohm max current: 1,1 A Modulation (MOD): yes MOD 1: 31,25 kHz	**CUTTING - CUT 2** max power: 80 Watt @ 600 Ohm max current: 1,1 A Modulation (MOD): yes	Similar - the differences do not affect safety and effectiveness

Manufacturer	Sutter Medizintechnik GmbH		Significant Differences
Trade Name	**CURIS® II RF Generator**	**CURIS® RF Generator**	
	Subject Device	Predicate	-
	MOD 2: 55 Hz 33%	MOD 1: 31,25 kHz MOD 2: no	
	COAGULATION - CONTACT max power: 90 Watt @ 500 Ohm max current: 1,2 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: 55 Hz 33%	**COAGULATION - CONTACT** max power: 80 Watt @ 400 Ohm max current: 1,2 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: 50 Hz	Similar - the differences do not affect safety and effectiveness
	COAGULATION - SOFTSPRAY max power: 70 Watt @ 700 Ohm max current: 0,9 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: no	**COAGULATION - SOFTSPRAY** max power: 60 Watt @ 600 Ohm max current: 0,9 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: no	Similar - the differences do not affect safety and effectiveness
Operating Modes - Bipolar	**CUTTING - BICUT** max power: 80 Watt @ 300 Ohm max current: 1,2 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: no	**CUTTING - EXCISE** max power: 80 Watt @ 300 Ohm max current: 1,2 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: no	Identical, renamed to BICUT
	-	**CUTTING - BICUT 1** max power: 80 Watt @ 300 Ohm max current: 1,3 A Modulation (MOD): no MOD 1: no MOD 2: no	The mode BICUT 1 Is not any more offered.

Manufacturer	Sutter Medizintechnik GmbH		Significant Differences
Trade Name	**CURIS® II RF Generator**	**CURIS® RF Generator**	
	Subject Device	Predicate	-
	-	**CUTTING - BICUT 2** max power: 80 Watt @ 300 Ohm max current: 1,2 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: no	The mode BICUT 2 Is not any more offered.
	COAGULATION - MACRO max power: 80 Watt @ 60 Ohm max current: 2,2 A Modulation (MOD): yes MOD 1: no MOD 2: 50 Hz	**COAGULATION - MACRO** max power: 80 Watt @ 50 Ohm max current: 2,2 A Modulation (MOD): yes MOD 1: no MOD 2: 50 Hz	Similar - the differences do not affect safety and effectiveness
	COAGULATION - PRECISE max power: 50 Watt @ 60 Ohm max current: 1,7 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: 50 Hz	**COAGULATION - PRECISE** max power: 50 Watt @ 50 Ohm max current: 1,7 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: 50 Hz	Similar - the differences do not affect safety and effectiveness
	COAGULATION - RAVOR max power: 40 Watt @ 60 Ohm max current: 1,7 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: 50 Hz	**COAGULATION - RAVOR** max power: 40 Watt @ 50 Ohm max current: 1,6 A Modulation (MOD): yes MOD 1: 31,25 kHz MOD 2: 50 Hz	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	identical

Manufacturer	Sutter Medizintechnik GmbH		Significant Differences
Trade Name	**CURIS® II RF Generator**	**CURIS® RF Generator**	
	Subject Device	Predicate	-
Electromagnetic Compatibility	IEC 60601-1-2 all applicable requirements met	IEC 60601-1-2 all applicable requirements met	identical

Both the **Sutter CURIS® RF Generator** and the **Sutter CURIS® RF Generator** are designed to be used with compatible electrosurgical mono and bipolar radiofrequency electrodes.

XII. Animal studies

Data from animal studies were not required to support the safety and effectiveness of the Sutter CURIS® II RF Generator.

XIII. Clinical Studies

Clinical data were not required to support the safety and effectiveness of the Sutter CURIS® II RF Generator. All validation was performed based on non-clinical performance tests.

XIV CONCLUSIONS

Based on the similar intended use, the same basic technological characteristics and performance testing, the Sutter CURIS® II RF Generator is substantially equivalent to the predicate device Sutter CURIS® RF Generator (K171869). The minor differences raise no new issues of safety and effectiveness, as the design differences have no effect on the performance, function or intended use.