



Food and Drug Administration
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September 10, 2015

Sutter Medizintechnik GmbH
Ulrike Zeissler
Manager, Regulatory Affairs
Tullastrasse 87
79108 Freiburg
Germany

Re: K150959

Trade/Device Name: Sutter Bipolar Forceps - Calvian

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: April 1, 2015

Received: April 1, 2015

Dear Zeissler:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

David Krause -S

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

Indications for Use

510(k) Number (if known)

K150959

Device Name

Sutter Bipolar Forceps - Calvian

Indications for Use (Describe)

Intended Use: Sutter Bipolar Forceps- Calvian are intended to remove tissue and control bleeding.

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 for K150959

APPLICANT: SUTTER MEDIZINTECHNIK GMBH
 DEVICES: SUTTER BIPOLAR FORCEPS - Calvian

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Section 807.92(c)

Date: 807.92(a)(1)	March 31, 2015
Submitter: 807.92(a)(1)	<p><u>Name:</u> SUTTER MEDIZINTECHNIK GmbH</p> <p><u>Address:</u> Tullastrasse 87 79108 Freiburg Germany</p> <p><u>Managing Director:</u> Bert Sutter</p> <p><u>Telephone:</u> +49 (0) 761 51551-0</p> <p><u>Fax:</u> +49 (0) 761 51551-30</p> <p><u>Contact person:</u> Ulrike Zeissler</p> <p><u>Telephone:</u> +49 (0) 761 51551-14</p> <p><u>E-mail:</u> zeissler@sutter-med.de</p>
Product: 807.92(a)(2)	<p><u>Trade Name:</u> Sutter Bipolar Forceps - Calvian</p> <p><u>Classification:</u> Class II; CFR 21 § 878.4400</p> <p><u>Common Name:</u> Electrosurgical Instruments and Accessories</p> <p><u>Product Code and Classification Name:</u> GEI - Electrosurgical Cutting & Coagulation Device & Accessories</p>
Predicate Device: 807.92(a)(3)	<p>Predicate device to which Sutter Bipolar Forceps - Calvian are claimed to be substantially equivalent is manufactured by</p> <ul style="list-style-type: none"> • Xomed Surgical Products, Microfrance Electrosurgical Instruments, various, (K993655)
Device Description: 807.92(a)(4)	<p>Sutter Bipolar Forceps - Calvian is an electrosurgical tool available in different handle styles and tip sizes. It is constructed with medical grade stainless steel, coated with Polyamide PA 11 as electrical insulator and possesses tips made of stainless steel that are partly not insulated. The forceps can be connected through an appropriate bipolar cable with the bipolar output of an electrosurgical generator. As an electrosurgical accessory it is intended to remove tissue and control bleeding. The maximum peak voltage to use the forceps is 500 Vp. The forceps are provided non-sterile, are reusable and must be sterilized prior initial and subsequent use.</p>
Intended Use: 807.92(a)(5)	<p>Intended Use: Sutter Bipolar Forceps - Calvian are intended to remove tissue and control bleeding.</p>

510(k) Summary for K150959

APPLICANT: SUTTER MEDIZINTECHNIK GMBH

DEVICES: SUTTER BIPOLAR FORCEPS - Calvian

Substantial Equivalence:	Sutter Bipolar Forceps - Calvian are substantial equivalent to the predicate devices since the basic features, design and intended uses are the same.		
	Feature	Sutter Calvian	Predicate device K993655
	Intended Use	As shown above under Intended Use	Same
	Branches Style	Angled	Straight, angled
	Dimensions		
	Tip size [mm]:	0.7– 2.5	1.3 – 2.5
	Material		Same
	Tips:	Stainless steel	
	Coating:	Polyamide (PA) 11	
	Connector:	Stainless steel/Plastic material	
	Base material:	Stainless steel	
	Bipolar	yes	Same
	Meets IEC 60601-2-2	yes	Same
Maximum peak voltage	500 Vp	833 Vp	
Sterility	Non-sterile, reusable	Same	
Sterilization method	Steam-sterilisation by user	Same	