October 4, 2019

SUTTER MEDIZINTECHNIK GmbH
Mr. Ulrike Zeissler
Manager, Regulatory Affairs
Tullastrasse 87
79108 Freiburg, Germany

Re: K192128
Trade/Device Name: Sutter ARROWtip Monopolar Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 1, 2019
Received: August 7, 2019

Dear Mr. 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. 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 located 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.

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 801and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Long Chen, Ph.D.
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

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)*
K192128

Device Name
Sutter ARROWtip™ Monopolar Electrodes

Indications for Use *(Describe)*
The ARROWtip™ Single-Use monopolar electrode is an electrosurgical instrument for precision soft tissue dissection. It is a single-use device intended for cutting, dissecting and cauterizing soft tissue. The ARROWtip™ Single-Use monopolar electrode is not intended for use in the central nervous system or in the central circulatory system.

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 OF SAFETY AND EFFECTIVENESS

Section 807.92

Date:	October 2nd, 2019	
Submitter:	Name: Address: Contact person: Titel: Telephone: Fax:	SUTTER MEDIZINTECHNIK GmbH Tullastrasse 87 79108 Freiburg Germany Ulrike Zeissler Manager Regulatory Affairs +49 (0) 761 51551-14 +49 (0) 761 51551-30
Product:	Trade Name: Common Name: Classification name: Product Code: Regulation Number: Classification: Classification Panel:	Sutter ARROW*tip*™ Monopolar Electrodes Monopolar Electrodes Electrosurgical, cutting & coagulation & Accessories GEI CFR 21 § 878.4400 Class II General and Plastic Surgery
Predicate Device:	Predicate device to which Sutter ARROW*tip*™ Monopolar Electrodes are claimed to be substantially equivalent is manufactured by • Stryker Leibinger, Stryker Leibinger Colorado MicroDissection Needles® (K033232)	
Device Description:	Sutter ARROW*tip*™ Monopolar Electrodes are electrosurgical instruments. The electrodes are provided with different angled electrode front parts and in different lengths. They are to be connected through an appropriate monopolar handpiece with the monopolar output of an electrosurgical generator. The electrodes are provided sterile and are single-use instruments.	
Intended Use:	The ARROWtip™ Single-Use monopolar electrode is an electrosurgical instrument for precision soft tissue dissection. It is a single-use device intended for cutting, dissecting and cauterizing soft tissue. The ARROWtip™ Single-Use monopolar electrode is not intended for use in the central nervous system or in the central circulatory system.	

Technological Characteristics:

The table below provides a comparison between the subject device and the predicate device

	Sutter ARROW*tip*™ Monopolar Electrodes	Predicate device K033232
Sheath	Straight / angled	Straight / angled
Dimensions Tip size [mm]:	Ø 0.8	Ø 0.5 mm
Material	Tungsten, stainless steel, PTFE	Tungsten, stainless steel, PTFE, Polyolefin
Meets IEC 60601-1	yes	yes
Meets IEC 60601-1-2	yes	yes
Meets IEC 60601-2-2	yes	yes
Meets ISO 10993-1	yes	yes
Sterility Assurance Level	10^{-6}	10^{-6}
Sterilization Method	Ethylene Oxide	Ethylene Oxide

Non-Clinical Performance Data:

The following performance data has been obtained for the substantial equivalence determination.

Bench Testing
Performance testing has been executed in line with the internal R&D process and in compliance with the proposals and recommendations of the 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 were carried out with respect to following subject areas:

Performance Data Bench Tests	
Test	**Conclusion**
Electromagnetic Compatibility and Electrical Safety	Pass
Mechanical strength and functionality performance testing	Pass
Thermal effects on tissue	Pass

Electromagnetic Compatibility and Electrical Safety Testing
Electrical and electromagnetic tests were performed to demonstrate that design specifications and performance requirements are met. Compliance to the voluntary standards IEC 60601-1 (AAMI/ANSI ES60601-1:2005), IEC 60601-2-2 and IEC 60601-1-2 has been shown.

Mechanical strength and functionality performance testing
Mechanical strength and functionality performance testing was performed to demonstrate that design specification are met.

	Mechanical stress tests showed that the design specification are met. **Thermal effects on tissue** Thermal effects on tissue testing was performed to determine thermal effects cased by the Sutter ARROW*tip*™ Monopolar Electrodes at different modes and power levels in comparison to the predicate device. Three different types of tissue were used and tests were performed in triplicate. Visual comparison as well as digital morphometric measurement using histology showed equivalent coagulation / cutting performance of subject device and predicate device. **Sterilization** Sutter ARROW*tip*™ Monopolar Electrodes are sterilized by using a validated ethylene oxide cycle. The sterilization cycle has been validated to ensure a sterility level of (SAL) 10^{-6} in accordance with ISO 11135. **Shelf Life Testing** Shelf-life testing has been conducted in accordance ISO 11607-1. The aging studies established that the Sutter ARROW*tip*™ Monopolar Electrodes and packaging remain functional and maintain sterility for up to 3 years. **Biocompatibility Testing** Biological evaluation and Biocompatibility testing has been performed in compliance to ISO 10993-1 Fourth edition 2009-10-15, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”. **Animal Studies** No animal studies have been performed as appropriate verification and validation of the subject device has been achieved based on comparison to the predicate device and from results of the bench testing, biocompatibility evaluation, and electrical / safety testing. **Clinical Studies** No clinical studies have been performed as appropriate verification and validation of the subject device has been achieved based on comparison to the predicate device and from results of the bench testing, biocompatibility evaluation, and electrical / safety testing.
Conclusion:	Sutter ARROW*tip*™ Monopolar Electrodes are substantially equivalent to the predicate device since the intended use, design, material and basic features are the same. 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.