April 5, 2018

Gunter Bissinger Medizintechnik GmbH
Mr. Matthias Bissinger
CEO
Hans-Theisen-Str. 1
D-79331 Teningen, DE Baden-Wurttemberg, Germany

Re: K172368
Trade/Device Name: Bipolar Micro-Coagulation Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 2, 2018
Received: March 12, 2018

Dear Mr. Bissinger:

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)*
K172368

Device Name
Bipolar Micro-Coagulation Forceps

Indications for Use *(Describe)*
Bipolar Micro-Coagulation Forceps 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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K172368

510(k) Summary

DATE OF APPLICATION: 2017-08-04

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1. Device Name

Product code: GEI
Trade Names: Bipolar Micro-Coagulation Forceps
Common Name: Electrosurgical, Cutting & Coagulation & Accessories
Classification Name: Electrosurgical cutting and coagulation device and accessories

2. Classification Product Code / Subsequent Code

Bipolar Micro-Coagulation Forceps can be classified according to following device name and product code

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Electrosurgical, Cutting & Coagulation & Accessories	General & Plastic Surgery	General & Plastic Surgery	GEI	2	878.4400

3. Prior Submissions

There have been no prior submissions of the subject devices so far.

4. Predicate Device

Predicate Device	510(k) Number	510(k) Holder
Sutter Bipolar Forceps – Calvian	K150959	Sutter Medizintechnik GmbH

5. Device Description

Bipolar Micro-Coagulation Forceps are electrosurgical tools available with different handles and different tip designs. The Bipolar Micro-Coagulation Forceps can be connected through an appropriate bipolar cable to an electrosurgical generator. The Bipolar Micro-Coagulation Forceps can be disassembled for cleaning and sterilization. The Bipolar Micro-Coagulation Forceps are delivered in unsterile condition and have to be sterilized prior to each use.

6. Indications for Use

The Bipolar Micro-Coagulation Forceps are intended to remove tissue and control bleeding.

7. Technological Characteristics

The technological characteristics of our Bipolar Micro-Coagulation Forceps are the same as the technological characteristics of the predicate device.

7.1. Device characteristics table

Company	Günter Bissinger Medizintechnik GmbH	Sutter Medizintechnik GmbH	Result
Device Name	Bipolar Micro-Coagulation Forceps	Sutter Bipolar Forceps – Calvian	-
Regulation Number	878.4400	878.4400	Substantially Equivalent
Code	GEI	GEI	Substantially Equivalent
Class	II	II	Substantially Equivalent
510(k) number	-	K150959	-
Indication for Use	Bipolar Micro-Coagulation Forceps are intended to remove tissue and control bleeding	Sutter Bipolar Forceps – Calvian are intended to remove tissue and control bleeding	Substantially Equivalent
Prescription / OTC	Prescription	Prescription	Substantially Equivalent

Company	Günter Bissinger Medizin-technik GmbH	Sutter Medizintechnik GmbH	Result
Device Design	Bipolar Micro-Coagulation For-ceps are electrosurgical tools available with different handles and different tip designs.	Sutter Bipolar Forceps – Calvian is an electrosurgical tool availa-ble in different handle styles and tip sizes.	Substantially Equivalent
Material	Stainless Steel Plastic Material	Stainless Steel Plastic Material	Substantially Equivalent
Tip size [mm]	0.35 – 2.8	0.7 – 2.5	Substantially Equivalent
Shaft Length [mm]	15	18	Substantially Equivalent
HF-mode	bipolar	bipolar	Substantially Equivalent
Maximum peak voltage [Vp]	300	500	Substantially Equivalent
Delivered Condition	unsterile	unsterile	Substantially Equivalent
single use	no	no	Substantially Equivalent
Meets IEC 60601-2-2	yes	yes	Substantially Equivalent

7.2. Summary of technological characteristics

The proposed device is similar in terms of design, operating principles and intended use and has similar technological characteristics as the predicate device. Both devices are bipolar forceps with the same intended use. Both devices are available with different handles and different tip sizes. They are both reusable devices which are delivered in unsterile condition. The subjected device as well as the predicate devices meet the requirements of IEC 60601-2-2.

8. Performance Data

Verification and validation results demonstrate that the device performs as intended and that the device is substantially equivalent to the predicate device K150959.

8.1. Biocompatibility

The device has been evaluated for its biological safety according to ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process”. Following endpoints have been assessed during the evaluation:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

The evaluation proofs the biological safety of the Bipolar Micro-Coagulation Forceps.

8.2. Electrical Safety

The Bipolar Micro-Coagulation Forceps has been tested according to IEC 60601-1 and IEC 60601-2-2.

The test setup included:

- Mechanical stability
- Insulation of active equipment
- High frequency leakage current
- High frequency electrical strength
- Power frequency (50 Hz)

The device had passed all performed tests.

8.3. Sterilization and Shelf Life

The devices are supplied in non-sterile condition and have to be cleaned prior to the first and every further use. A cleaning procedure as well as a sterilization procedure have been validated.

8.4. Thermal Effects on Tissue

To evaluate the thermal effects on tissue a comparison test between the Bipolar Micro-Coagulation forceps of Bissinger and the predicate device was performed. Three different tissue types were used. Each tissue type was tested with different power settings. Afterwards the thermal damage was analyzed.

The comparison of the two devices showed that they are both substantially equivalent. Their functions and characteristics did not display any major difference throughout the tests.

9. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, Bipolar Micro-Coagulation Forceps are considered substantially equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications. The performed tests show that the subjected device is in compliance with the applicable recognized standards. Performed comparison testing with the predicate device shows substantial equivalence to the FDA-cleared predicate device Sutter Bipolar Forceps – Calvian.

There are no differences between the devices which would raise new issues of safety or effectiveness.

The Bipolar Micro-Coagulation Forceps is substantially equivalent to predicate device Sutter Bipolar Forceps – Calvian cleared under 510(k) #K150959