11/17/2022

Guenter Bissinger Medizintechnik GmbH
Matthias Bissinger
Managaing Director
Hans-Theisen-Str. 1
Teningen, Baden-Wurttemberg 79331
Germany

Re: K213042
Trade/Device Name: Supra Non-Stick Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 14, 2022
Received: October 20, 2022

Dear Matthias 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. 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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing 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,

Jessica Carr -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213042

Device Name
SUPRA Non-Stick Bipolar Forceps

Indications for Use *(Describe)*

The Bissinger SUPRA Non-Stick Bipolar Forceps are used for grasping, dissection and coagulation of biological tissues. The fully assembled instrument (if assembly is needed) has to be connected – with the appropriate cable - to the bipolar output of an HF generator.
Supra Non-Stick Bipolar Forceps may not be used for tubal sterilization or tubal coagulation.

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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Günter Bissinger Medizintechnik GmbH
SUPRA Non-Stick Bipolar Forceps
510(k) Premarket Notification

DATE OF APPLICATION: 16.09.2021

APPLICANT:

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1 Device Name

Trade Name: SUPRA Non-Stick Bipolar Forceps

Common Name: Bipolar Forceps

Device Classification Name: Electrosurgical, Cutting & Coagulation & Accessories

2 Classification / Product Code

SUPRA Non-Stick Bipolar Forceps can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical cutting and coagulation device and accessories	General & Plastic Surgery	General & Plastic Surgery	GEI	878.440	2

3 Predicate Device / Reference Device

Device	Predicate Device	510(k) Number	510(k) Holder
SUPRA Non-Stick Bipolar Forceps	Claris Non-Stick Bipolar Forceps	K051429	Günter Bissinger Medizintechnik GmbH

4 Device Description

SUPRA Non-Stick Bipolar Forceps are available in several working length and tip width. They are delivered with a 2-pin plug to connect them to bipolar output of an HF generator. The devices are supplied in sterile state and are intended for single use only.

5 Intended Use

The Bissinger SUPRA Non-Stick Bipolar Forceps are used for grasping, dissection and coagulation of biological tissues. The fully assembled instrument (if assembly is needed) has to be connected – with the appropriate cable - to the bipolar output of an HF generator.

Contraindication:

Supra Non-Stick Bipolar Forceps may not be used for tubal sterilization or tubal coagulation.

6 Technological Characteristics

The technological characteristics of SUPRA Non-Stick Bipolar Forceps are the same as the technological characteristics of the predicate device.

6.1 Device Characteristics Table

Company	Günter Bissinger Medizintechnik GmbH (New Device)	Günter Bissinger Medizintechnik GmbH (Predicate Device)	Result
Device Name	SUPRA Non-Stick Bipolar Forceps	Claris Non-Stick Bipolar Forceps	---
Regulation Number	878.440	878.440	---

Company	Günter Bissinger Medizintechnik GmbH (New Device)	Günter Bissinger Medizintechnik GmbH (Predicate Device)	Result
Class	II	II	Substantially Equivalent
Code	GEI	GEI	Substantially Equivalent
510(k) number	---	K051429	---
Indication for Use	The Bissinger SUPRA Non-Stick Bipolar Forceps are used for grasping, dissection and coagulation of biological tissues. The fully assembled instrument (if assembly is needed) has to be connected – with the appropriate cable - to the bipolar output of an HF generator. Supra Non-Stick Bipolar Forceps may not be used for tubal sterilization or tubal coagulation.	The Bissinger CLARIS Non-Stick bipolar forceps are designed to grasp, manipulate and coagulate selected tissue. It is to be connected through a suitable bipolar cable with the bipolar output of an electro-surgical generator. Bipolar For-ceps must only be used with bipolar coagulation current. The Bissinger CLARIS Non-Stick bipolar forceps has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.	Substantially Equivalent
Prescription / OTC	Prescription	Prescription	Substantially Equivalent
Device Design	Insulated forceps with plug	Insulated forceps with plug	Substantially Equivalent
Tip Size [mm]	0.5-1.5	0.25-2.0	Substantially Equivalent
Shaft Length [mm]	101-229	110-240	Substantially Equivalent
HF Mode	Bipolar	Bipolar	Substantially Equivalent
Maximum peak voltage [V_P]	Ref. no. 91511106: 300 Ref. no. 906xxxxx, 91512601: 500	300	Substantially Equivalent
Delivered condition	Sterile	Unsterile	Substantially Equivalent
Single use	Yes	No	Substantially Equivalent
Materials	Stainless Steel Plastic Material Ag800	Stainless Steel Plastic Material Ag800	Substantially Equivalent

6.2 Summary of Technological Characteristics

The proposed devices are similar in terms of design, operating principles and intended use and have similar technological characteristics as the predicate devices. The materials used on these devices are also used in the legally marketed predicate devices.

7 Sterilization and Shelf Life

The product is delivered in sterile condition. No treatment is required prior to its use. Its shelf life is 5 years. It is intended for single-use only and as such, is not intended to be reprocessed and sterilized. Appropriate packaging, shelf-life, and sterilization validations were carried out, which prove the sterility of the products.

8 Biocompatibility

The devices have been evaluated concerning their biological safety (according to ISO 10993-1). The material, the manufacturing process, as well as the packaging have been considered within this biological safety evaluation. Based on the evaluation of the material constituents, the devices meet the requirements of ISO 10993-1. The biological safety of the devices is therefore considered to be satisfactory demonstrated.

9 Electrical Safety

Tests according to IEC 60601-1, IEC 60601-2-2 and IEC 60601-1-2 have been performed.
The device had passed all performed tests.

10 Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, our SUPRA Non-Stick Bipolar Forceps are considered to be substantially equivalent to the predicate device Claris Non-Stick Bipolar Forceps in terms of indication for use, materials and technology, design and performance specifications. There are no differences between the devices which would raise new issues of safety or effectiveness.