October 8, 2019

Faulhaber Pinzetten OHG
Ms. Dorothea Faulhaber
General Manager
Daimlerstr. 1
D-78665 Frittlingen
Germany

Re: K182773
Trade/Device Name: Single-Use Non-Stick Bipolar Forceps sterile/non-sterile
Single-Use Non-Stick Bipolar Irrigating forceps sterile/non-sterile

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 5, 2019
Received: August 8, 2019

Dear Dorothea Faulhaber:

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 and Part 809); 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,

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)*
K182773

Device Name
Single Use Non-Stick Bipolar Forceps sterile/ non-sterile
Single Use Non-Stick Bipolar Irrigating Forceps sterile/ non-sterile

Indications for Use *(Describe)*
Faulhaber Single Use Non-Stick Bipolar Forceps sterile/ non-sterile and Single Use Non-Stick Bipolar Irrigating Forceps sterile/ non-sterile are intended for use by a physician familar with electrosurgery for bipolar coagulation and irrigation of tissue for general surgery. The bipolar forceps are used with the bipolar output for standard electrosurgical generators.
The products are intended for single use and are provided sterile as well as non-sterile.
Products supplied non-sterile must be cleaned, disinfected and sterilized prior to their use by the validated cleaning, disinfection and sterilization process.
The bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

The types of surgery intended are
- General surgery
- Laryngeal coagulation
- Orthopedic coagulation
- Thoracic coagulation
- Neurosurgical coagulation
- Gynecological coagulation (except for use in female sterilization)
- Urological coagulation
- Ear-, Nose-, Throat 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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510 (k) Summary

1. Submitter's Contract Information

FAULHABER PINZETTEN OHG
Daimlerstr. 1
D – 78665 Frittlingen
Telephone: 00497426 - 96 38 53-0
Fax: 00497426 – 96 38 53-30
Contact Person: Ms. Dorothea Faulhaber, CEO
Contact Person: Ms. Patricia Pfaff, Quality Management
Date prepared: 06/Oct/2019

2. Device name and classification

Trade name: Single Use Non-Stick Bipolar Forceps sterile/ non sterile
Single Use Non-Stick Bipolar Irrigating Forceps sterile/ non sterile
Common name: Single Use Bipolar Forceps
Classification name: Electrosurgical, Cutting & Coagulation & Accessories
Product code: GEI
Regulation number: 878.4400
Classification: Class II
Predicate Device: K101080 Egon Faulhaber Pinzetten
Reference Devices: K080187 Olsen Medical

3. Predicate devices

3.1 Primary predicate device

	Device Owner/ Trade Name	510(k) #	Product Code
Primary Predicate Device	Egon Faulhaber Bipolar, Non-Stick Bipolar and Monopolar Forceps	K101080	GEI Electrosurgical, Cutting & Coagulation & Accessories Class II

3.2 Reference device

	Device Owner/ Trade Name	510(k) #	Product Code
Reference Device	Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps	K080187	GEI Electrosurgical, Cutting & Coagulation & Accessories Class II

4. Device Description

The product family “Single Use Bipolar Forceps”, including Faulhaber Single Use Non-Stick Bipolar Forceps and Single Use Non-Stick Bipolar Irrigating Forceps, are intended to be used for bipolar coagulation and irrigation of tissue by physicians familiar with bipolar coagulation in medical practices and clinics.
The Single Use Bipolar Forceps are single use products and must not be reused. They are provided sterile as well as non-sterile. Products delivered non sterile must be cleaned, disinfected and sterilized before use.
For the application the Single Use Bipolar Forceps have to be connected by appropriate bipolar cable to the bipolar output of an HF generator. Bipolar cables and ESU are not part of the subject device.

The Single Use Bipolar Forceps are provided in bayonet design with non-stick tips and are identical in design, construction, materials and manufacturing to the reusable device EGON FAULHABER Bipolar Non-Stick Forceps (K101080). The principles of operation and mechanism of action are identical as well.
In addition to the cleared and legally marketed EGON FAULHABER devices, the products are with irrigation function available. The irrigation function works via a drain running along the forceps tines from tip to handle. At handle height, the drain is connected by Luer-Lock via an irrigation tubing with an irrigation pump.

5. Intended Use/ Indications for use

Faulhaber Single Use Non-Stick Bipolar Forceps sterile/ non-sterile and Single Use Non-Stick Irrigating Forceps sterile/ non-sterile are intended for use by a physician familiar with electrosurgery for bipolar coagulation and irrigation of tissue for general surgery. The bipolar forceps are used with the bipolar output for standard electrosurgical generators. The products are intended for single use and are provided sterile as well as non sterile. Products supplied non sterile must be cleaned, disinfected and sterilized prior to their use by the validated cleaning, disinfection and sterilization process.
The bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

The types of surgery intended are

- General surgery
- Laryngeal coagulation
- Orthopedic coagulation
- Thoracic coagulation
- Neurosurgical coagulation
- Gynecological coagulation (except for use in female sterilization)
- Urological coagulation
- Ear-, Nose- and Throat coagulation

6. Substantial Equivalence discussion

	Subject Device K182773 Single Use Bipolar Forceps (sterile and non-sterile) Faulhaber Pinzetten OHG	**Primary Predicate Device K101080** Bipolar, Non-Stick Bipolar and Monopolar Forceps EGON FAULHABER Pinzetten	**Reference Device K080187** Single Use Bayonet Bipolar Irrigating Forceps Olsen Medical
510(k) number	K182773	K101080	K080187
510(k) submitter/holder	Faulhaber Pinzetten OHG	EGON FAULHABER Pinzetten	Olsen Medical
Product Code	GEI	GEI	GEI
Indications for Use/ Intended Use	Faulhaber Single Use Non-Stick Bipolar Forceps and Single Use Non-Stick Bipolar Irrigating Forceps are intended for use by a physician familar with electrosurgery for bipolar coagulation and irrigation of tissue for general surgery. The bipolar forceps are used with the bipolar output for standard electrosurgical generators. The products are intended for single use and are provided sterile as well as non-sterile. Products supplied non-sterile must be cleaned, disinfected and sterilized prior to their use by the validated cleaning, disinfection and sterilization process. The bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used	The EGON FAULHABER Bipolar, Non-Stick Bipolar and Monopolar Forceps are intended for use by a physician familar with electrosurgery in bipolar and monopolar coagulation for general surgery where coagulation of soft tissue is needed. The Bipolat Forceps are used with the bipolar and the Monopolar Forceps are used with with the monopolar output for standard electrosurgical generators. The EGON FAULHABER Bipolar, Non-Stick Bipolar and Monopolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for this procedures. The types of surgery intended are - General surgery	The Olsen Medical Single Use Bayonet Biopolar Irrigating Forceps is a single use product sold sterile and is intended for use in electro surgery for coagulation and irrigation of tissue. This device is intended for use with the OLSEN MEDICAL Integrated Irrigation Tubing and Bipolar Cord Set or similar design of Bipolar Cord and Irrigation Tubing.

	Subject Device K182773 Single Use Bipolar Forceps (sterile and non-sterile) Faulhaber Pinzetten OHG	**Primary Predicate Device K101080** Bipolar, Non-Stick Bipolar and Monopolar Forceps EGON FAULHABER Pinzetten	**Reference Device K080187** Single Use Bayonet Bipolar Irrigating Forceps Olsen Medical
	for these procedures. The types of surgery intended are - General surgery - Laryngeal coagulation - Orthopedic coagulation - Thoracic coagulation - Neurosurgical coagulation - Gynecological coagulation (except for use in female sterilization) - Urological coagulation - Ear-, Nose-, and Throat coagulation	- Laryngeal coagulation - Orthopedic coagulation - Thoracic coagulation - Neurosurgical coagulation - Gynecological coagulation (except for use in female sterilization) - Urological coagulation - Ear-, Nose-, and Throat coagulation	
Product life	Single use	Reusable	Single use
Application Technology	Bipolar	Bipolar and monopolar	Bipolar
Tip dimensions/ Tip material	0.5 mm – 1.5 mm Sterling silver	0.25 mm – 2.0 mm Sterling silver	0.5 mm – 1.5 mm Non-Stick Cermet (Ceramic Metal) Coating
Shaft style/ Shaft dimensions/ Shaft materials	Bayonet	Straight/ Angled/ Bayonet	Bayonet
	203 mm – 300 mm	110 mm – 250 mm	180 mm – 267 mm
	Coated Stainless steel	Coated Stainless steel	Insulated stainless steel body
Cable connector type	US-Pin	US-Pin	Twin Pin
Irrigation connector type	Female luer to be connected with male luer of irrigation tubing	not applicable	Female luer for use with the Olsen medical Integrated Irrigation Tubing and Bipolar Cord Set or similar design of Bipolar Cord and Irrigation Tubing
Body contact material	- Stainless steel acc. ISO 7153-1 - Sterling silver	- Stainless steel acc. ISO 7153-1 - Sterling silver	- Stainless steel body with nylon insulation - Non-stick Cermet

	Subject Device K182773 Single Use Bipolar Forceps (sterile and non-sterile) Faulhaber Pinzetten OHG	**Primary Predicate Device K101080** Bipolar, Non-Stick Bipolar and Monopolar Forceps EGON FAULHABER Pinzetten	**Reference Device K080187** Single Use Bayonet Bipolar Irrigating Forceps Olsen Medical
	- Rilsan® (Nylon) Coating	- Rilsan® (Nylon) Coating	(Ceramic Metal) coating
Delivery status	Sterile and non-sterile	Non sterile	Sterile
Sterilization method for products provided sterile	Gamma irradiation	not applicable	Ethylene Oxide (EtO)
Packaging for products provided sterile	Cleerpeel® Foil Pouch	not applicable	Tyvek® Pouch
Sterilization method for initial treatment/ reprocessing	Steam sterilization	Steam sterilization	not applicable
Packaging for products provided non-sterile	foil bag with cardboard box	foil bag with cardboard box	not applicable
Maximum Peak Voltage	≤ 500 V_p	≤ 500 V_p	Information not available
Tissue temperature range	~ 60°C - ~ 100°C	~ 60°C - ~ 100°C	Information not available
Method of operation	mechanical activation, no switch	both, mechanical activation (bipolar) and handle with switch (monopolar)	mechanical activation, no switch
Accessories	No	No	Olsen medical Integrated Irrigation Tubing and Bipolar Cord Set or similar design of Bipolar Cord and Irrigation Tubing
Safety features	Dielectric strength insulation acc. IEC 60601-2-2; insulated safety plug	Dielectric strength insulation acc. IEC 60601-2-2; insulated safety plug	Insulated

This submission supports the position that the Faulhaber Pinzetten OHG forceps is substantially equivalent to a number of previously cleared devices, including Olsen Medical Single Use Bayonet Irrigating Bipolar Forceps.

7. Performance data:

Performance testing of the product family Single Use Bipolar Forceps was determined by the application of a risk management process acc. ISO 14971:2013-04.

As a result of the risk analysis and regarding the applicable FDA guidance documents, the following tests have been identified as essential.

The indicated performance tests were derived and have been projected. The performance data were provided in support of the substantial equivalence determination.

7.1 Drop Test acc. DIN EN 22248:1993-02 (ISO 2248:1985) "Packaging; complete, filled transport packages; vertical impact test by dropping"
The vertical impact test was conducted on Faulhaber Single Use Bipolar Forceps acc. to DIN EN 22248:1993-02 (ISO 2248:1985).
The products in their primary and outer packaging have passed the tests without damage.
The outer packaging is in a transportable condition.
The test of the packaging system has been successfully completed, the vertical impact test demonstrated the suitability of the packaging system successfully.

The test results are sufficient to support substantial equivalence of the subject device with the predicate devices.

7.2 Electrical safety acc. DIN EN IEC 60601-2-2:2018-12 (IEC 60601-2-2:2017)
Electrical safety testing was conducted on Faulhaber Single Use Bipolar Forceps.
The instruments have completed the entire test cycles without changes or impairments, in particular to insulation, but also in terms of mechanics and function.
The testing of the instruments for dielectric strength therefore have been completed successfully.
The system complies with the DIN EN IEC 60601-2-2:2018-12 (IEC 60601-2-2:2017) standards for electrical safety.

The test results are sufficient to support substantial equivalence of the subject device with the predicate devices.

7.3 Performance Tests "Mechanical strength/ Electrical performance with all components and accessories as a system/ Thermal effects on tissue"
Performance tests regarding mechanical strength, electrical performance with all components and accessories as a system and thermal effects on tissue have been conducted on Faulhaber Single Use Bipolar Forceps.
The test procedures correspond to the FDA Guidance document "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery – Guidance for Industry and Food and Drug Administration Staff", issued August 15, 2016.

For the test performance regarding thermal effects on tissue, three different types of tissue (liver, kidney and muscle) were coagulated with the Single Use Non-Stick Bipolar Forceps with irrigation function and without irrigation function at different settings. For comparison, all tests were carried out with the product “Faulhaber Pinzetten OHG Non-Stick Bipolar Forceps bayonet, reusable”.
The tests were carried out in accordance with the Guidance for industry and food and drug administration staff “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery” from August 15, 2016.
All test results met the pre-defined acceptance criteria.
The evaluation of the results also included a comparison between products with irrigation function and products without irrigation function. This comparison allows the conclusion that products with irrigation function achieve the same results, with maximum power setting even better result than the products without irrigation function.

The performance test showed that the products of the product family “Single Use Bipolar Forceps” are able to provide, with or without irrigation of tissue during coagulation, safe and appropriate results for the intended use.

The test results are sufficient to support substantial equivalence of the subject device with the predicate devices.

8. Biocompatibility:

The Biological Evaluation of the Single Use Bipolar Forceps was conducted in accordance with use of International Standard ISO-10993-1:2018 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process,” as recognized by FDA.
Based on the risk management it was proven, that the Single Use Bipolar Forceps are manufactured from identical material using identical processes and procedures as the primary predicate device K101080. Identical machines and equipment as well as identical operating- and auxiliary materials are used in production processes. Therefore, additional clinical tests are not necessary, because the safety for use of the materials has been proved in the past and will continue to be monitored by Post Market Surveillance.

The results of the Biological Evaluation are appropriate to support substantial equivalence of the subject device with the predicate device.

9. Conclusion

The subject device is identical in design, material and manufacturing with the primary predicate device. Regarding the deviations from the primary predicate device in single usage, irrigation function and sterile condition, the subject device is similar to the predicate device.
Regarding these aspects, the performance testing has been conducted and successfully passed.
The results of nonclinical testing demonstrate that the subject device is as safe and effective and performs as well as the predicate devices.

For these reasons we conclude that the subject device K182773 is substantially equivalent to the cleared and legally marketed predicate devices K101080 and K080187.