January 25, 2024

Sutter Medizintechnik GmbH
℅ Arne Briest
Managing Director
VISAMED GmbH
Kastellstr. 8
Karlsruhe, 76227
Germany

Re: K233425
Trade/Device Name: FlexTip Bipolar electrodes single-use (AR-S9805-0028), FlexTip Bipolar electrodes single-use (AR-S9805-0035)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 12, 2024
Received: January 12, 2024

Dear Arne Briest:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.01.25 13:48:57 -05'00'

Mark Trumbore, 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)*
K233425

Device Name
FlexTip Bipolar electrodes single-use

Indications for Use *(Describe)*
The RF instruments are used for tissue and vessel coagulation (hemostasis) by means of radiofrequency current.

The products are intended for use in endoscopically performed or supported surgeries.

The types of surgery intended are:
• Endoscopic procedures
• Orthopedic procedures
• Neurosurgical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K233425

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92 upon which substantial equivalence is based.

I SUBMISSION SPONSOR and APPLICATION CORRESPONDANT

A. SUBMISSION SPONSOR

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B. APPLICATION CORRESPONDANT

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Contact Person :

Arne Briest

CEO

arne.briest@visamed.com

II. Dated prepared: January 23, 2024

III DEVICE IDENTIFICATION

Name of Device:	**FlexTip bipolar electrodes single-use**
Common Name:	**FlexTip bipolar electrodes single-use**
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories (21 CFR § 878.4400)
Classification Panel:	General & Plastic Surgery
Regulatory Class:	II
Product Code:	GEI
510k #:	TBD

IV PREDICATE DEVICE

K170377 – TipControl RF Instrument, bipo

V. DEVICE DESCRIPTION

FlexTip Bipolar electrodes single-use consist of a handpiece with electrode front part, cable and plug. The Bipolar electrodes are available in two different working lengths. The FlexTip electrodes are encoded for RF generators Arthrex Inc. (AR-S9800 Synergy) and Sutter Medizintechnik GmbH (K171869 CURIS® RF Generator). The electrodes are provided sterile and are single-use instruments. Electrode shaft and tips are made of stainless steel and are insulated with PEBAX tubing.

Model list (REF)	Working length (mm)	Tips (mm)
AR-S9805-0035	350	2
AR-S9805-0028	280	2

VI INDICATIONS FOR USE

The RF instruments are used for tissue and vessel coagulation (hemostasis) by means of radiofrequency current.

The products are intended for use in endoscopically performed or supported surgeries.

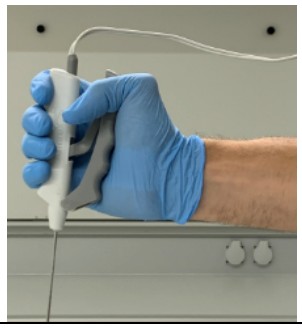
The types of surgery intended are:

- Endoscopic procedures
- Orthopedic procedures
- Neurosurgical coagulation

VII COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The **TipControl RF Instrument, bipo** is the predicate device for the **FlexTip Bipolar electrodes single-use**.

	Predicate Devices	**Subject Device**	**Comparison Analysis**
Device	**RF Instrument BIPO**	**FlexTip**	**-**
Prescription use	x	x	identical
Device Identification			
	Richard Wolf Medical Instruments Corp.	**Sutter Medizintechnik GmbH**	-
Regulation Number and – Name	21CFR878.4400 Electrosurgical cutting and coagulation device and accessories	21CFR878.4400 Electrosurgical cutting and coagulation device and accessories	identical
Regulatory Class	II	II	identical
Product Code	GEI	GEI	identical
510(k) number	K170377	TBD	-
Description and Indication for Use			
General Device Description	Steril, disposable single-use, bipolar radiofrequency (RF) instrument used for tissue and vessel coagulation (hemostasis) by means of radio-frequency current.	Steril, disposable single-use, bipolar radiofrequency (RF) instrument used for tissue and vessel coagulation (hemostasis) by means of radio-frequency current.	**Identical**
Indications for use	The RF instruments are used for tissue and vessel coagulation (hemostasis) by means of radiofrequency current. The products are intended for use in endoscopically performed or supported surgeries. The types of surgery intended are: - Endoscopic Procedures - Orthopedic coagulation - Neurosurgical coagulation	The RF instruments are used for tissue and vessel coagulation (hemostasis) by means of radiofrequency current. The products are intended for use in endoscopically performed or supported surgeries. The types of surgery intended are: - Endoscopic procedures - Orthopedic procedures - Neurosurgical coagulation	**Identical**

	Predicate Devices	Subject Device	Comparison Analysis
Biological Characteristics			
Duration of Contact	Time related to the procedure	Time related to the procedure	**Identical**
Contact with body fluids/tissue	Yes	Yes	**Identical**
Sterility	Instruments are provided sterilized by ETO to a SAL 10^{-6}.	Instruments are provided sterilized by ETO to a SAL 10^{-6}.	**Identical**
Meets ISO 10993-1	Yes	Yes	**Same**
Technical Characteristics			
Electrode Design	Bended tips	Bended tips	**Identical**
Handle Design			**Identical working principle,** different design of handle design (grip). The differences do not affect safety and effectiveness.
Diameter of the Electrode Tip	2 mm	2 mm	**Identical**
Working length	280 mm 350 mm	280 mm 350 mm	**Identical**
Material Tips, Branches Handle Insulation	 Stainless steel, two components glue polymer polymer	 Stainless steel, two components glue polymer polymer	 **Same** **Same** **Same**
Product Packaging	PTEG Blister Tyvek pouch Cardbox	PTEG Blister Tyvek pouch Cardbox	**Same materials, different size because of the different handle design.**
Combination with radiofrequency generator	4 MHz	4 MHz	**Same**
Maximum peak voltage	400 Vp	400 Vp	**Same**
Compliance to FDA recognized electrical safety standards			
Meets IEC 60601-1	Yes	Yes	**Same**
IEC 60601-2-2	Yes	Yes	**Same**
IEC 60601-1-2	Yes	Yes	**Same**
IEC 60601-2-18	Yes	Yes	**Same**

Both the **TipControl RF Instrument, bipo** and the **FlexTip Bipolar electrodes single-use** are designed to be used with compatible electrosurgical bipolar radiofrequency generators.

VIII NON-CLINICAL PERFORMANCE DATA

The following performance data were provided in support of 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, issued on March 9, 2020.

Tests were carried out with respect to following subject areas:

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

Electrical safety and electromagnetic compatibility

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the **FlexTip Bipolar electrodes single-use**.

The device complies with FDA recognized electrical safety standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-2
- IEC 60601-2-18

Electrical and electromagnetic tests were performed to demonstrate that design specifications and performance requirements are met.

Mechanical strength and functionality performance testing

Mechanical strength and functionality performance testing was performed to demonstrate that design specifications are met. Mechanical stress tests showed that the design specifications are met.

Thermal effects on tissue

Thermal effects on tissue testing were performed to determine thermal effects caused by the **FlexTip Bipolar electrodes single-use** at different power levels and application times 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 performance of subject device and predicate device.

Systems Performance / Bench-top Validation

The system performance / bench-top Validation testing was performed to demonstrate that design specifications are met. The testing evaluated both the **FlexTip Bipolar electrodes single-use** and the interaction with the Sutter CURIS® RF generator.

Systems Performance / Bench-top Validation tests showed that the design specifications are met.

Biocompatibility testing

The biocompatibility evaluation for **FlexTip Bipolar electrodes single-use** has been conducted in accordance with FDA Guidance Document: Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” and ISO 10993-1 – “Biological evaluation of medical devices – Evaluation and testing within a risk management system”. These **FlexTip Bipolar electrodes single-use** are categorized as externally communicating devices in indirect contact with tissue/bone for a limited time (<24h) *per* ISO 10993-1. The evaluation reveals that biocompatibility requirements are met by the **FlexTip Bipolar electrodes single-use**.

Biocompatibility testing was performed on the **FlexTip Bipolar electrodes single-use** in accordance with:

• ISO 10993-1 - Biological evaluation of medical devices- Evaluation and testing within a risk management system.

Sterilization Validation

In addition, the sterilization validation on the **FlexTip Bipolar electrodes single-use** has been performed in accordance with:

- ISO 11135 - Sterilization of health care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical device;
- ISO 11737-1 - Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
- ISO 11137-2 - Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 14937 - Sterilization of health care products - General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices; and
- ISO 10993-7 - Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) data shows that the limit of EO < 4 mg and ECH < 9 mg after 9 days of aeration (gas release) that remain on the **FlexTip Bipolar electrodes single-use** will not be exceeded. The sterility assurance level (SAL) was 10^{-6}. Package and product integrity of the tube sets were tested in accordance with ISO11607-1 - Packaging for terminally sterilized medical devices and ASTM-F- 1980 - Standard for accelerated aging of sterile medical device packages.

Shelf Life Testing

Shelf-life testing has been conducted in accordance ISO 11607-1. The aging studies established that the **FlexTip Bipolar electrodes single-use** and packaging remain functional and maintain sterility for up to 1 year.

Animal studies

Data from animal studies were not required to support the safety and effectiveness of the **FlexTip Bipolar electrodes single-use**.

Clinical Studies

Clinical data were not required to support the safety and effectiveness of the **FlexTip Bipolar electrodes single-use**. All validation was performed based on non-clinical performance tests.

IX CONCLUSIONS

Based on the similar intended use, the same basic technological characteristics and performance testing, the **FlexTip Bipolar electrodes single-use** is substantially equivalent to the predicate device **TipControl RF Instrument, bipo** (K170377). 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.