May 29, 2024

Varian Medical Systems, Inc.
Lynn Allman
Sr. Director Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

Re: K240784
Trade/Device Name: Temperature Sensor Probe (ABL-18TP20)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: March 20, 2024
Received: March 21, 2024

Dear Lynn Allman:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.05.29 13:06:28 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240784

Device Name
Temperature Sensor Probe

Indications for Use *(Describe)*
The Temperature Sensor Probe, used with Varian ablation systems, is intended for monitoring tissue temperature near the ablation site.

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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PREMARKET NOTIFICATION

510(k) Summary

Temperature Sensor Probe

The following information is provided as required by 21 CFR 807.92

I. Submitter's Information:

Name and Address:	Varian Medical Systems Inc.
	9825 Spectrum Drive, Building 2 Austin, TX 78717
Contact Name:	Lynn Allman, Senior Director Regulatory Affairs
E-mail:	submissions.support@varian.com
Date Prepared:	May 29, 2024

II. Device Information:

Proprietary Name:	Temperature Sensor Probe
Common/ Usual Name:	System, Ablation, Microwave and Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4400
Product Code	NEY

III. Predicate Device 510(k):

Emprint™ Ablation System with Thermosphere Technology: K200796

Predicate Device within K200796 identified to claim Substantial Equivalence:
Ablation Remote Temperature Probe (RTP20).

IV. Subject Device Description:

Temperature Sensor Probe is an optional accessory designed for use with compatible Varian ablation systems. Principal components of the temperature sensor probe include:

- Needle
- Handle
- Lead cable and connector

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V. Intended Use/ Indications for Use Statement:

The Temperature Sensor Probe, used with Varian ablation systems, is intended for monitoring tissue temperature near the ablation site.

VI. Substantial Equivalence Discussion:

The following table compares the subject device to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence.

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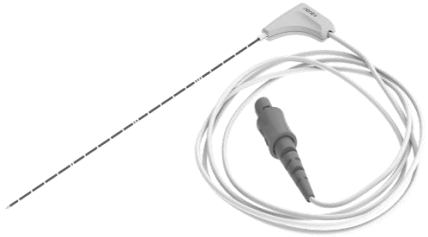
Table 1: Summary of the comparison of technological characteristics between the predicate and subject devices

Features/ Characteristics	**Subject Device** Temperature Sensor Probe	**Predicate Device (**K200796) Ablation Remote Temperature Probe	**Differences**
Device representative image			
Intended Use/ Indications for Use	The Temperature Sensor Probe, used with Varian ablation systems, **is intended for monitoring tissue temperature near the ablation site.**	The RTP20 remote temperature probe is for use with the Emprint Ablation System with Thermosphere Technology to **monitor tissue temperature at or near the ablation site.** The remote temperature probe can be used with the Emprint Ablation Generator with Thermosphere Technology to automatically disable microwave	Both the subject and the predicate devices **have the same intended use of monitoring tissue temperature in ablation procedures.** The predicate's additional design feature mentioned in the indications of use statement has no impact on the overall intended use/ indications of use of the device.

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Features/ Characteristics	**Subject Device** Temperature Sensor Probe	**Predicate Device (**K200796) Ablation Remote Temperature Probe	**Differences**
		energy when it measures a temperature of 45° C (default setting). Use of the RTP20 in an ablation procedure is optional.	
Compatible Systems and their intended use/ indications of use	IntelliBlate Microwave Ablation System under FDA review (K240480) *The IntelliBlate Microwave Ablation System is intended for coagulation (ablation) of soft tissue in laparoscopic, intraoperative, and percutaneous ablation procedures, including partial or complete ablation of non-resectable liver tumors.*	Emprint™ Ablation System with Thermosphere Technology *The Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, endoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors.*	Same

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Features/ Characteristics	**Subject Device** Temperature Sensor Probe	**Predicate Device (**K200796) Ablation Remote Temperature Probe	**Differences**
	The IntelliBlate Microwave Ablation System is not intended for use in cardiac procedures.	*The Emprint™ Ablation System is not intended for use in cardiac procedures.*	
Operating Principle	Measures the tissue temperature in real time via a thermocouple within the tip of the probe.	Measures the tissue temperature in real time via a thermocouple within the tip of the probe.	Same
Product code, FDA regulation and device class	NEY, 21 CFR 878.4400 and Class II	NEY, 21 CFR 878.4400 and Class II	Same
Manufacturer	Varian Medical Systems	Covidien	Different manufacturer
Prescription (Rx only)	Yes	Yes	Same
Optional Accessory	Yes	Yes	Same
Measuring Site	Tissue near ablation site	At or near ablation site	Similar
Temperature Range (Temperature Accuracy)	10°C-60°C (±2°C)	37°C-60°C (±1.5°C)	Similar performance specifications. Representation of the reported temperature on the User Interface of the compatible ablation

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Features/ Characteristics	**Subject Device** Temperature Sensor Probe	**Predicate Device (**K200796) Ablation Remote Temperature Probe	**Differences**
			system used with the subject device are rounded to nearest integer to enhance usability.
Thermocouple-based temperature sensor at the tip of the needle	Yes	Yes	Same
Signal Processing and Display on the compatible ablation system	Real time, continuous display of tissue temperature	Real time, continuous display of tissue temperature	Same
Tissue Contact per ISO 10993-1	External communicating device, in contact with tissue/bone/dentin and limited contact duration (A) (<24 hours)	External communicating device, in contact with tissue/bone/dentin and limited contact duration (A) (<24 hours)	Same
Design and Construction			
Principle Components	Needle, handle and lead cable	Needle, handle, lead cable and cannula with stylet	Thicker needle shaft of the subject device eliminates the use of a cannula
Rigid Construction	Yes	Yes	Same

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Features/ Characteristics	**Subject Device** Temperature Sensor Probe	**Predicate Device (**K200796) Ablation Remote Temperature Probe	**Differences**
Distal Tip configuration	Trocar Tip	Rounded non-sharp tip on Temperature Probe used together with a sharp cannula	Sharp Trocar Tip replaces the use of a cannula
Right Angle Probe	Yes	Yes	Same
Needle Shaft length	20cm	20 cm	Same
Needle Gauge inserted in the tissue	18G	18G Cannula (18G) with stylet inserted with 20.5G needle.	Similar. Overall gauge size is the same, however the predicate uses a cannula with a stylet and thinner probe needle. Thicker wall of the subject device's needle shaft provides mechanical stiffness that eliminates the use of a cannula and stylet.
Cannula and Stylet	No	Yes	Thicker wall of the needle shaft of the subject device provides mechanical stiffness that eliminates the use of a cannula and stylet.

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Features/ Characteristics	**Subject Device** Temperature Sensor Probe	**Predicate Device (**K200796) Ablation Remote Temperature Probe	**Differences**
Needle Thermocouple	Soldered at the tip	Soldered at the tip	Same
Patient Contacting Components	Needle Shaft and needle tip	Needle: Needle Shaft and needle tip Cannula: Cannula tip Stylet: Stylet tip	Same. Thicker wall of the needle shaft of the subject device provides mechanical stiffness that eliminates the use of a cannula and stylet
Probe handle with Printed Circuit Board Assembly (PCBA)	Yes	No	Different design. The predicate device converts the probe analog temperature to digital signal inside the console and sends the information to the display. The subject device converts the probe analog temperature to digital signal in the handle (PCBA) and sends the information to the console display.
Materials			

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Features/ Characteristics	**Subject Device** Temperature Sensor Probe	**Predicate Device (**K200796) Ablation Remote Temperature Probe	**Differences**
Patient Contacting Materials	Stainless Steel	Stainless Steel	Same
Lead Cable Outer Jacket	PVC	TPV	Different polymer; thermoplastic elastomer similar to the predicate device.
Handle Plastic	ABS	ABS	Same
Thermocouple	T-Type	T-Type	Same
Safety Standard Compliance	IEC 60601-1, 60601-1-6, 60601-2-6, 60601-1-2	IEC 60601-1, 60601-1-6, 60601-2-6, 60601-1-2	Same
Biocompatibility	All the patient-contacting materials are evaluated by the biocompatibility standard ISO 10993-1.	All the patient-contacting materials are evaluated by the biocompatibility standard ISO 10993-1.	Same
Software	No	No	Same
Device Usage	Single-use, disposable, optional accessory	Single-use, disposable, optional accessory	Same
Sterilization	ETO	ETO	Same

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Features/ Characteristics	**Subject Device** Temperature Sensor Probe	**Predicate Device (**K200796) Ablation Remote Temperature Probe	**Differences**
Packaging configuration and materials	Tyvek sterile barrier pouch within a cardboard shelf carton box sealed with a tamper tape.	Thermoform tray and single Tyvek sterile barrier lid within a SBS (solid bleached sulfate) shelf carton box sealed with a tamper paper tape.	Different packaging (less footprint)

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VII. Performance Data:

1. Non-clinical Testing:

Temperature Sensor Probe underwent non-clinical testing to demonstrate the design and performance of the device meets the established design criteria. The subject device successfully completed functional intended use support and reliability testing. To support substantial equivalence in performance with the predicate device, the subject and predicate devices underwent side-by-side testing for performance i.e accuracy of temperature monitoring. The test results established that the subject device is substantially equivalent to the predicate device in performance and is as safe and effective as the predicate device.

2. Non-clinical Animal Testing:

Animal testing completed with Temperature Sensor Probe to validate usability and performance of the device on porcine soft tissue models complies with the United States Food and Drug Administration Good Laboratory Practice (GLP) Regulations, 21 CFR Part 58.

3. Clinical Data/ Testing:

No clinical data/ testing is included within the submission.

4. Sterilization:

Temperature Sensor Probe is sterilized utilizing 100% ethylene oxide gas to ensure a minimum sterility assurance level of 10^{-6} in accordance with ISO 11135, ISO 10993-7, ISO 11138-1, ISO 11737-1 and ISO 11737-2.

5. Software, Cybersecurity, and Interoperability

Temperature Sensor Probe does not contain software. Software verification related to functionality of Temperature Sensor Probe with IntelliBlate Microwave Ablation System complies with IEC 62304 – "Medical device software – software life cycle processes "and FDA Guidance "Content of Premarket Submissions for Device Software Functions."

6. Temperature Monitoring:

Temperature monitoring testing completed in accordance with FDA Guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" demonstrates that the temperature sensing under simulated conditions meets design specification and performance requirements.

7. Biocompatibility:

Biocompatibility testing of the Temperature Sensor Probe in accordance with ISO 10993-1 demonstrates that the patient-contacting components are biocompatible.

8. Electrical Safety and Electromagnetic Compatibility:

Temperature Sensor Probe complies with applicable IEC 60601 series of standards: IEC 60601-1, IEC 60601-1-6, IEC 60601-2-6, and IEC 60601-1-2.

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9. Packaging Integrity and Shelf Life:

Packaging integrity and shelf-life testing complies with ISO 11607-1 and ISO 11607-2.

VIII. Conclusion:

The performance data for the Temperature Sensor Probe support the safety of the device and the verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. Varian considers Temperature Sensor Probe to be as safe and effective as the predicate device and therefore, substantially equivalent to the predicate device, Ablation Remote Temperature Probe cleared along with Emprint Ablation System in K200796.