April 15, 2025

Stryker Instruments
Josh Measures
Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K250327
Trade/Device Name: OptaBlate Radiofrequency (RF) Generator System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 5, 2025
Received: March 19, 2025

Dear Josh Measures:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.04.15 16:20:11 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250327

Device Name
OptaBlate Radiofrequency (RF) Generator System

Indications for Use *(Describe)*
The intended use of the OptaBlate Radiofrequency (RF) Generator System is as follows:
• Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.
• Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standards therapy.
• Ablation of benign bone tumors such as osteoid osteoma.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Submitter Information

This Premarket Notification is submitted by:

510(k) Owner	Stryker Instruments 1941 Stryker Way Portage, MI 49002 USA
Contact Person	Josh Measures Staff Regulatory Affairs Specialist Email: josh.measures@stryker.com
Registration Number	3015967359
Date Summary Prepared	April 15, 2025

Device Name

Table 1 - Subject Device Information

Subject Device Information	
Trade/Proprietary Name	OptaBlate Radiofrequency (RF) Generator System
Classification Name	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Classification Panel	General & Plastic Surgery
Product Code	GEI
Device Class	Class II

Predicate Device

The legally marketed predicate for the subject device is detailed in Table 2.

Table 2 - Predicate Device Information

Predicate Device Name	510(k)	Product Code	Manufacturer
OptaBlate Radiofrequency (RF) Generator System	K221074	GEI	Stryker Instruments

Indications for Use

The intended use of the OptaBlate Radiofrequency (RF) Generator System is as follows:

- Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.
- Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standards therapy.
- Ablation of benign bone tumors such as osteoid osteoma.

Contraindications

Use of the OptaBlate™ RF System is contraindicated in vertebral body levels of C1 through C7.

Device Description

The device description of the OptaBlate Radiofrequency (RF) Generator System remains consistent with that of the previously cleared K221074, with no modifications other than the incorporation of the OptaBlate Curve 10mm, 15mm, and 20mm Probe Single Kits.

The OptaBlate Curve Probe Kits provide flexible probes with microinfusers that are used with OmniCurve 10G Fracture Kits, the OptaBlate RF Generator and the Splitter Cable. Together they enable a unipedicular approach for bone tumor ablation. The access tools from the OmniCurve Kits create a curved, unipedicular pathway to the bone tumor. Based on tumor size, a flexible probe size is selected and inserted into the curved pathway. Then with the microinfuser (which reduces impedance events), the OptaBlate RF Generator and the Splitter Cable, the bone tumor is ablated.

Substantial Equivalence Comparison

The predicate device has been identified as the OptaBlate Radiofrequency (RF) Generator System RF Generator (K221074). Both the subject and predicate device share the same intended use, and indications for use and technological characteristics. Results of verification and validation demonstrate that these differences do not introduce new questions of safety and effectiveness. The subject devices are at least as safe and effective as the predicate device.

Table 3 – Intended Use Comparison

Description	Subject Device	Predicate Device
	OptaBlate Radiofrequency (RF) Generator System	**OptaBlate™ Radiofrequency (RF) Generator system**
Classification	Class II	Class II
Product Code	GEI	GEI
Regulation	21 CFR 878.4400	21 CFR 878.4400
Regulation Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Indications for Use	The OptaBlate™ RF Ablation System is intended for: • Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. • Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy. • Ablation of benign bone tumors such as osteoid osteoma.	The OptaBlate™ RF Ablation System is intended for: • Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. • Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy. • Ablation of benign bone tumors such as osteoid osteoma.
Anatomical Site	Bone	Bone
Method of Access	Percutaneous	Percutaneous
Approach	Unipedicular	Bipedicular

Table 4 – Technological Characteristics Comparison

Description	Subject Device	Predicate Device
	OptaBlate Radiofrequency (RF) Generator System	**OptaBlate™ Radiofrequency (RF) Generator system**
Energy Type	Radiofrequency Energy	Radiofrequency Energy
Principle of Operation	Operator controlled; RF delivered from compatible generator	Operator controlled; RF delivered from compatible generator
Compatible RF Generator	OptaBlate RF Generator	OptaBlate RF Generator
Operating Mode	Bipolar RF energy	Bipolar RF energy
Generator Maximum Output Energy	System: 30 W Per Channel: 7.5 W	System: 30 W Per Channel: 7.5 W
Generator Output Frequency	500 kHz	500 kHz
Feedback Mechanism	Temperature Controlled	Temperature Controlled

Summary of Non-Clinical Testing

The following tests were conducted to demonstrate substantial equivalence with the predicate device:

- Sterilization
- Biocompatibility
- Packaging
- Electrical Safety and EMC Testing

Testing requirements were determined by relevant standards and FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery*, issued March 9, 2020.

Performance Testing

A range of design verification testing was conducted to confirm the subject devices perform as intended and are safe and effective for their intended use in accordance with FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery,* issued March 9, 2020.

Summary of Clinical Testing

Clinical testing was not required for this Special 510(k).

Conclusion

The subject devices share the same intended use and fundamental operating principles as the legally marketed predicate devices. The modifications introduced do not raise new or different questions of safety or effectiveness. Testing results support a determination of substantial equivalence to the predicate device for the requested indications for use.