September 16, 2022

Stryker Corporation
Bruce Backlund
Principal Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K221074
Trade/Device Name: OptaBlate RF Generator, OptaBlate Probes, OptaBlate Microinfuser Infusion Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 10, 2022
Received: August 12, 2022

Dear Bruce Backlund:

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,

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)*
K221074

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 standard 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.

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510(K) SUMMARY

Date Prepared: September 09, 2022

Submitter Information:
Stryker Corporation
1941 Stryker Way
Portage, MI 49002

Establishment Registration: 1811755

Contact Information:
Bruce Backlund
Principal Regulatory Affairs Specialist
(763) 762-5902
bruce.backlund@stryker.com

Device Information:

Trade Name: OptaBlate™ Radiofrequency (RF) Generator System

Common Name: RF Generator

Classification Name: Electrosurgical cutting and coagulation device and accessories

Product Code: GEI

Regulation Number: Class II 21 CFR 878.4400

Predicate Devices: K182497 OsteoCool™ RF Ablation System

Reference Devices:
K170242 MultiGen™ 2 RF Generator System
K080451 Uniblate® System
K040989 RITA® System

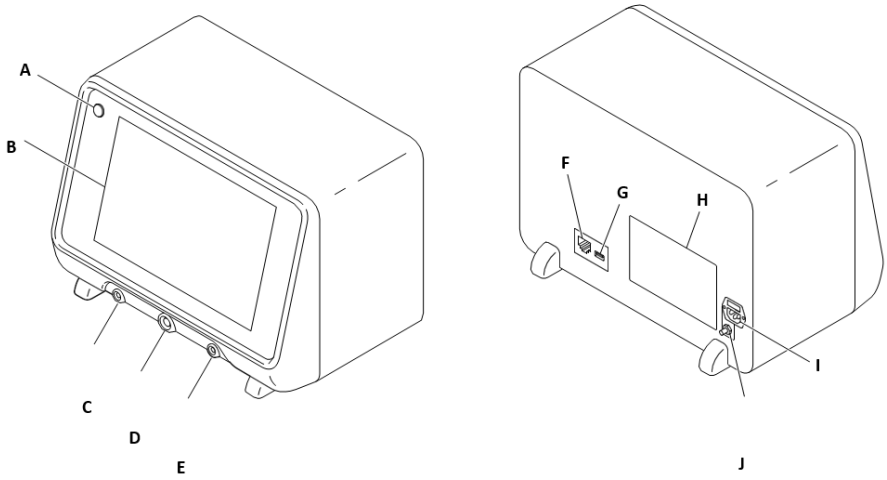
Device Description:

The OptaBlate™ Radiofrequency (RF) Generator system is a bipolar, high frequency electrosurgical system. The OptaBlate™ RF Generator will be used in conjunction with OptaBlate™ Probes, OptaBlate™ Microinfuser™ Infusion Device, OptaBlate 150 mm Temperature Sensor, MultiGen 2 Splitter Cable, and other currently marketed Stryker compatible accessories to produce lesions by the direct application of radiofrequency currents. The generator applies temperature-controlled, radiofrequency (RF) energy into the probe. During lesion creation, targeted tissue is exposed to RF energy using an active probe inserted into a cannula. The application of RF energy causes a thermal reaction at the targeted tissue site to

create a lesion. Each OptaBlate™ Radiofrequency (RF) Generator System is composed of a RF generator, a Splitter Cable, Temperature Sensor, and a choice of 4 disposable kit options. The kits contain disposable probes and infusion devices.

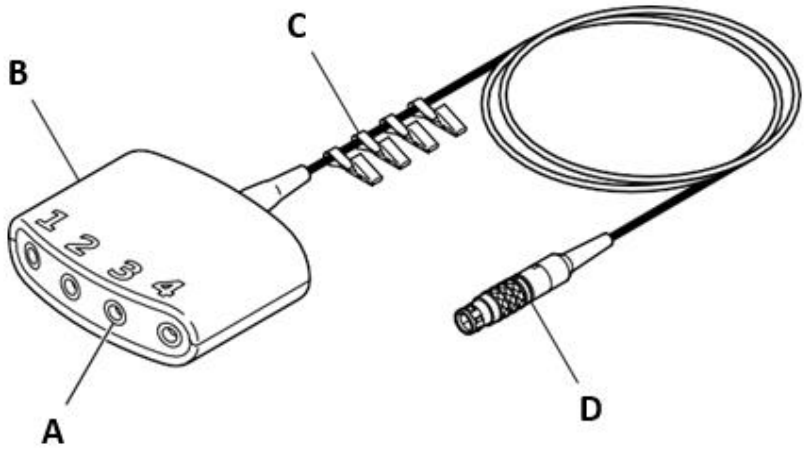
Part Number	**Item Name**	**Items Comprising Kit** ***(if applicable, list PN & name)***
9700-000-000	OptaBlate RF GENERATOR	Includes Generator
9700-815-015	OptaBlate 150MM TEMPERATURE SENSOR	To be sold a la carte
9700-015-100	OptaBlate 15MM PROBE SINGLE KIT	(1) 15MM PROBE (1) MICROINFUSER INFUSION DEVICE The kit components will not be available a la carte, only available as a kit Kit components are individually pouched and sterilized
9700-015-200	OptaBlate 15MM PROBE DUAL KIT	(2) 15MM PROBE (2) MICROINFUSER INFUSION DEVICE The kit components will not be available a la carte, only available as a kit Kit components are individually pouched and sterilized
9700-020-100	OptaBlate 20MM PROBE SINGLE KIT	(1) 20MM PROBE (1) MICROINFUSER INFUSION DEVICE The kit components will not be available a la carte, only available as a kit Kit components are individually pouched and sterilized
9700-020-200	OptaBlate 20MM PROBE DUAL KIT	(2) 20MM PROBE (2) Microinfuser INFUSION DEVICE The kit components will not be available a la carte, only available as a kit Kit components are individually pouched and sterilized
8400-800-000	MULTIGEN 2 SPLITTER CABLE	Currently available in an a la carte non -sterile configuration. The splitter cable will be included in the OptaBlate system IFU under the 'For use with' section. The splitter cable does not have its own IFU

Part Number	Item Name	Items Comprising Kit *(if applicable, list PN & name)*
9700-811-000	11 G Hand Drill	To be sold a la carte
0306-330-000	11 G (gauge) Access Cannula	To be sold a la carte
0406-650-400	RF Sterilization Case	To be sold a la carte
0406-630-225	CURVED CANNULA, 150MM, 20G, 10.0MM	To be sold a la carte
0406-620-325	STRAIGHT CANNULA, 150MM, 20G, 10.0MM	To be sold a la carte
0995-851-010	Power Cord, shielded, 3.7 m length, plug type B	Currently available in an a la carte non -sterile configuration.



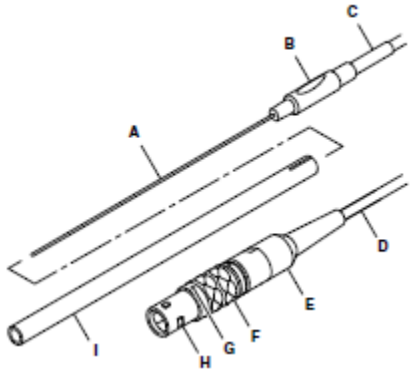
OptaBlate™ Radiofrequency (RF) Generator

A	**Power Button-** Allows generator to be switched to ready for use or standby power.	**B**	**Display Screen-** Provides a color, touch sensitive screen to select settings, enter data, and view status. The display screen provides operational status and messages.
C	**Grounding Pad Cable Receptacle-** Not active or used.	**D**	**Splitter Cable Receptacle-** Allows for the installation of the splitter cable connector.
E	**RF Hand Controller Cable Receptable-** Not active or used.	**F**	**Ethernet Receptacle-** Not active or used.
G	**USB Receptable-** Not active or used.	**H**	**Specification Label-** Contains model, part number and serial number information.
I	**Power Cord Receptable**	**J**	**Equipotential Grounding Lug-** Provides for the connection of a equipotential ground. The lug shall be used as a protective earth connection.



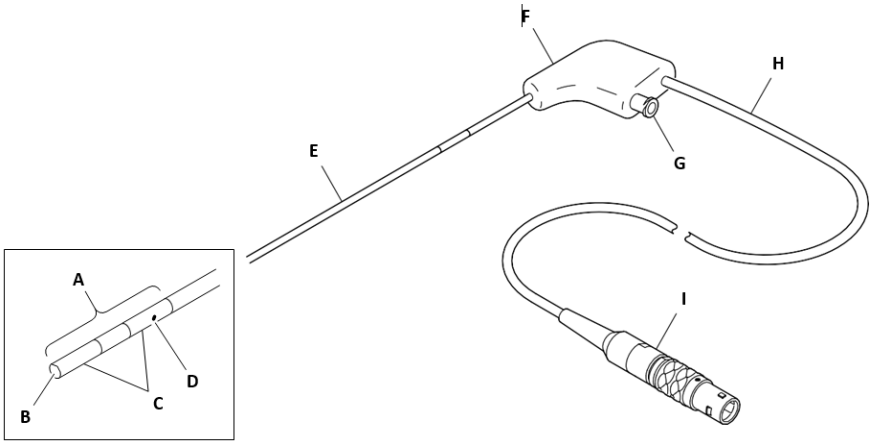
Splitter Cable

A	**Channel Receptacle (four)-** Allows for the installation of a disposable probe(s) or a reusable temperature sensor(s).	**B**	**Splitter Cable Housing-** Provides for the connection interface between the generator and a maximum of four accessories (probes/temperature sensors).
C	**Garment Clamps (four)-** Provides the means to support the cable when connected to surgical drape material.	**D**	**Splitter Cable Connector-** Allows for the installation of the splitter cable into the generator.



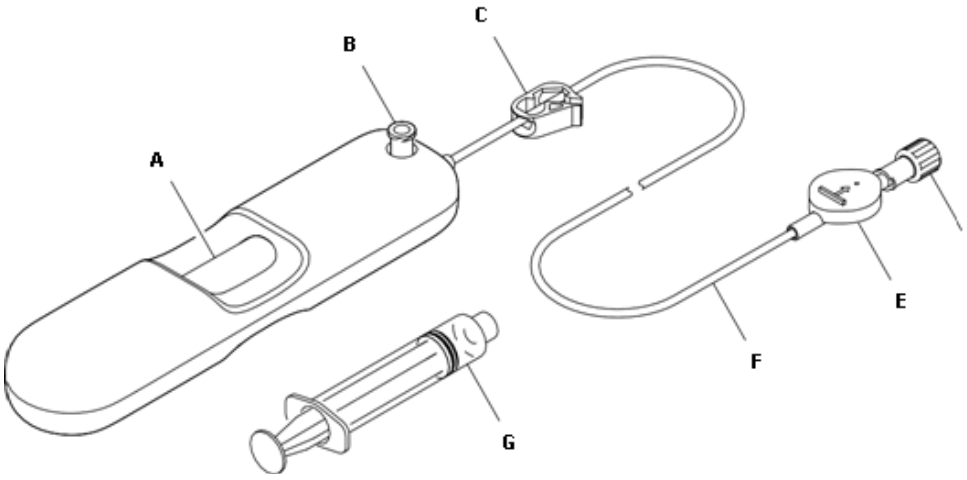
Temperature Sensor

A	**Sensor Probe-** Used to monitor and transmit temperature data from the surgical site.	**B**	**Sensor Hub-** Provides the connection interface between the probe and cable.
C	**Sensor Probe Strain Relief (color-coded)-** Provides cable strain relief and identifies the compatible cannula.	**D**	**Sensor Cable-** Used to transmit temperature data from the surgical site to the generator.
E	**Connector-end Strain Relief (color-coded)-** Provides cable strain relief.	**F**	**Connector Release Collar-**Used to remove connector from connector receptacle.
G	**Connector Alignment Mark-** Used to properly orient and install the connector into the connector receptable.	**H**	**Push-Pull Connector-** Used to install and release the temperature sensor into the generator connector receptacle.
I	**Protective Sleeve-** Provides protection for probe tip.		



Probe

A	**Active Tip Length** — Describes the length of the emitting surface used to transmit RF energy to the ablation zone.	**B**	**Thermocouple Tip** — Allows measurement of the temperature in the ablation zone.
C	**Radiopaque Probe Bands** — Allows for the visualization of the emitting RF energy surfaces using X-ray or fluoroscopic imaging technology.	**D**	**Microinfusion Orifice** — Provides saline from the Microinfuser to the ablation zone.
E	**Probe —** Provides the pathway for RF energy and saline to the ablation zone. Also allows temperature information to be collected at the ablation zone and provided to the generator.	**F**	**Probe Hub (color-coded)** — Provides the connection interface to the generator and the microinfuser.
G	**Probe Saline Port** — Allows for the connection of the micro-catheter connector and the Microinfuser saline source. Saline is provided to the tip of the probe to cool and hydrate the ablation zone.	**H**	**Probe Electrical Cable —** Provides for the electrical connection between the generator and the probe.
I	**Probe Cable Connector —** Allows for the installation of the probe cable into the splitter cable housing.		



Microinfuser with 6 mL Syringe

A	**Saline Reservoir (6 mL)** — Used to store NaCl saline.	**B**	**Syringe Port** — Allows connection of saline—filled syringe.
C	**Clamp** — Used to stop the regulated saline flow from the reservoir to prevent leakage during set up.	**D**	**Micro-catheter Connector** — Used to connect the micro- catheter to the probe saline port.
E	**Filter** — Used to remove air from the saline flowing to the ablation zone.	**F**	**Micro-catheter** — Allows for the automatic delivery of a regulated saline flow to the ablation zone.
G	**6 mL Syringe** — Used to fill the Microinfuser reservoir with saline.		

Indications for Use:

The intended use of the OptaBlate™ RF 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 standard 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.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the subject and predicate devices are equivalent. Both the subject device and the primary predicate device use the same modes of operation, types of control, energy delivery and type of energy output. None of the changes alter the operating principle, modes of operation, or temperature range. Both systems use the same type of accessories (connecting cables, probes and cannulae). The user interaction with the devices is similar. As demonstrated by the performance testing the subject device has similar performance specifications as the predicate device.

Intended Use Comparison			
	OptaBlate™ RF Ablation System **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**	**EXPLANATION OF DIFFERENCES**
510(k) Clearance	Subject Device of current Submission	K182497	Identical
Regulation Number	878.4400	878.4400	Identical
Product Code	GEI	GEI	Identical
Product Class	II	II	Identical
Indication 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	The OsteoCool™ 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	Identical

Intended Use Comparison			
	OptaBlate™ RF Ablation System **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**	**EXPLANATION OF DIFFERENCES**
	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.	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.	
User	Physicians (IR), Scrub Techs/Nurses, Central Sterile Techs	Physicians familiar with RF lesion techniques	Similar
Anatomical Site	Bone	Bone	Identical
Method of Access	Percutaneous	Percutaneous	Identical

RF System Technical Comparison			
FEATURE	***Stryker OptaBlate™ RF System*** **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**	**EXPLANATION OF DIFFERENCES**
Energy Type	Radiofrequency Energy	Radiofrequency Energy	Identical
Principle of Operation	Operator controlled; RF delivered from compatible generator	Operator controlled; RF delivered from compatible generator	Identical

RF System Technical Comparison			
FEATURE	***Stryker OptaBlate™ RF System*** **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**	**EXPLANATION OF DIFFERENCES**
Mechanism of Action	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	Identical
Rate of Temperature Rise in Sample Tissues	Controlled by RF Generator	Controlled by RF Generator	Identical
Feedback Mechanism	Temperature Controlled	Temperature Controlled	Identical
Active Electrode Length	15, 20 mm	7, 10, 15, 20 mm	Similar OptaBlate has fewer length options
Active Electrode Material	Stainless Steel per EN 1.4301 or EN 1.4307 (304 or 304L)	Stainless Steel per EN 1.4301 or EN 1.4307 (304 or 304L)	Similar
Electrode Insulation Material	Polyetheretherketone	Polyimide	Similar Both materials are common high-performance plastics known for high heat resistance. Verification and Validation was successfully conducted on the subject device and there were no questions of safety and efficacy raised.

RF System Technical Comparison			
FEATURE	***Stryker OptaBlate™ RF System*** **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**	**EXPLANATION OF DIFFERENCES**
Electrode Diameter	13 Gauge	17 Gauge	Similar Both sizes are considered percutaneous
Electrode Length	16 cm	16 cm	Identical
Electrode Sterilization	EO, Single Use	EO, Single Use	Identical
Compatible RF Generator	OptaBlate RF Generator	OsteoCool RF Generator	N/A
Generator Power Output Channels	4	2	Similar OptaBlate has a flexible configuration that allows 1 to 4 channels for power output.
Generator Maximum Output Energy	System: 30 W Per Channel: 7.5 W	System: 40 W Per Channel: 20W	Similar Optablate requires less power output.
Generator Maximum Voltage	System: 48.5 V_{RMS}	System: 130 V_{RMS}	Different OptaBlate requires much less power per channel, which necessitates less system voltage.

RF System Technical Comparison			
FEATURE	***Stryker OptaBlate™ RF System*** **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**	**EXPLANATION OF DIFFERENCES**
Generator Output Frequency	500 kHz	465 kHz	Similar Both frequencies are considered within the band for typical RF ablation and create equivalent lesion sizes. Verification and Validation was successfully conducted on the subject device and there were no questions of safety and efficacy raised.
Generator Maximum Current	System: 1.7 A_{RMS} Per Channel: 0.433 A_{RMS}	System: 1.0 A_{RMS} Per Channel: 0.5 A_{RMS}	Similar OptaBlate has a higher system current due to the increased number of output channels.
Default Ablation Temperature	95°C	70°C	Similar OsteoCool has a lower setpoint due to active tip cooling. Both systems will achieve up to 95°C in the

RF System Technical Comparison			
FEATURE	***Stryker OptaBlate™ RF System*** **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**	**EXPLANATION OF DIFFERENCES**
			tissue adjacent to the electrode. Verification and Validation was successfully conducted on the subject device and there were no questions of safety and efficacy raised.
Other System Components	• Splitter Cable 8400-800-000 • 15 mm Ablation Probe Single Kit 9700-015-100 • 15 mm Ablation Probe Dual Kit 9700-015-200 • 20 mm Ablation Probe Single Kit 9700-020-100 • 20 mm Ablation Probe Dual Kit 9700-020-200 • Temperature Sensor 9700-815-015 • 11G Drill 9700-811-000	• Hub OC04 • Single Probe Kit 7 mm OCP107 • Single Probe Kit 10 mm OCP110 • Single Probe Kit 15 mm OCP115 • Single Probe Kit 20 mm OCP120 • Dual Probe Kit 7 mm x2 OCP207 • Dual Probe Kit 10 mm x2 OCP210 • Dual Probe Kit 15 mm x2 OCP215 • Dual Probe Kit 20 mm x2 OCP220 • OCP220RF Pump OC02 • ITC 28G OCN001	Verification and Validation was successfully conducted on the subject device and there were no questions of safety and efficacy raised.

Infusion device Technical Comparison			
FEATURE	***OptaBlate™ Infusion Device*** **SUBJECT DEVICE**	***RITA® infusion device (K040989)*** **REFERENCE DEVICE**	**EXPLANATION OF DIFFERENCES**
Infuser	15 mm Probe Single Kit 9700-015-100 20 mm Probe Single Kit 9700-020-100 15 mm Probe Dual Kit 9700-015-200 20 mm Probe Dual Kit 9700-020-200	Intelliflow Pump 700-102941	N/A
Infusion Liquid	Saline	Saline	Identical.
Flow Rate Range	6 to 10 ml/hr	3 to 42 ml/hr	Similar. The OptaBlate Microinfuser operates within a smaller window of the reference device infusion range. Verification and Validation was successfully conducted on the subject device and there were no questions of safety and efficacy raised.
Disposable	Yes	Pump: No Tubing Set: Yes	Similar.

Infusion device Technical Comparison			
FEATURE	***OptaBlate™ Infusion Device*** **SUBJECT DEVICE**	***RITA® infusion device (K040989)*** **REFERENCE DEVICE**	**EXPLANATION OF DIFFERENCES**
			The OptaBlate Microinfuser and the RITA tubing set are both disposable items. The OptaBlate Microinfuser is completely disposable, while the RITA system utilizes a reusable peristaltic pump.

Substantial Equivalence

The indications for use and intended use of the subject device are the same as the predicate devices. The technological characteristics of the subject device are similar to the predicate devices, including: principle of operation, design, function, materials, biocompatibility, and sterility.

Performance Testing

Performance testing involved biocompatibility, design verification (dimensional, functional, strength, HFE/UE verification testing), electrical safety and electromagnetic compatibility, software, packaging, shelf life, design validation and Human Factors Engineering. Performance testing showed that the device meets design specifications and performs as intended.

Thermocouple Effects

Verification testing demonstrated that the relevant components of the subject OptaBlate RF Ablation system achieves accurate temperature measurements as per specified test requirements.

Comparative bench-top verification testing

Direct comparative bench top verification testing was completed to demonstrate the substantially equivalent ablation performance of the subject device and predicate OsteoCool™ RF Ablation System (K182497, S.E. 01/15/2019). Tissue models consisted of fresh chicken muscle and bovine bone. Following ablation, chicken muscle lesion length and width were

directly measured. Bovine bone lesions were indirectly measured via tissue temperature at a given ablation zone boundary. The results demonstrated that lesion dimensions achieved by the subject device are substantially equivalent to those obtained with the predicate device.

Clinical:

The purpose of the literature review provided herein is to demonstrate the safety and efficacy of radiofrequency ablation in for the following indications in eligible patients:

1) Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body
2) 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
3) Ablation of benign bone tumors, such as osteoid osteoma

A thorough review of the literature explored 1) the medical field and targeted treated populations applicable for the Optablate RF Generator System; 2) clinical data for predicate and similar devices; and 3) vigilance databases to assess safety. Performance was assessed using reported outcomes including clinical and technical success, improvements in pain through validated measures (VAS), and the need for repeat procedures. Safety was assessed through both peer-reviewed publications and vigilance databases for reported complications, with events that were specifically related to the device or procedure clearly highlighted.

Stryker identified a total of 175 unique publications utilizing search criteria specific to predefined indications. These were screened for inclusion using predetermined criteria and a weighted appraisal scoring system. In addition to vigilance databases, a thorough full-text review of 41 manuscripts was performed providing supportive clinical efficacy and safety data that covered all stated intended indications.

Results from the literature search conclude that RF ablation devices are safe and effective. RF ablation consistently resulted in decreased patient pain post procedure regardless of indication. Furthermore, safety events were primarily due to underlying conditions or the use of cement post procedure. Overall, this search supports that the potential benefits from this device / treatment outweigh the potential risks.

Conclusion

Based on the comparison of intended use and technological characteristics, the device is similar to the predicate device. The hardware and software verification and validation testing demonstrate that the subject device meets its performance specifications and will perform as intended in the specified use conditions and that any differences between the subject device and predicate device do not raise new questions of safety and effectiveness. Therefore, the subject device can be found substantially equivalent to the predicate device.