**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 25, 2017

Stryker Corporation
David Colao
Senior Manager Regulatory Affairs
4100 E. Milham Ave
Kalamazoo, Michigan 49001

Re: K170242
Trade/Device Name: MultiGen™ 2 RF Generator System
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD, GXI
Dated: April 25, 2017
Received: April 26, 2017

Dear Mr. Colao:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K170242

Device Name
Stryker MultiGen™ 2 RF Generator System

Indications for Use *(Describe)*

Stryker MultiGen™ 2 RF Generator
The Stryker MultiGen™ 2 RF Generator, in combination with the Stryker MultiGen 2 Electrodes and RF Cannulae, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

Venom MultiGen 2 Electrodes
The Stryker Venom MultiGen 2 Electrodes, in combination with the Stryker RF Cannulae and Stryker MultiGen™ 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerve, and nerve roots for the relief of pain.

Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

Standard MultiGen 2 Standard Electrodes
The Stryker MultiGen 2 Electrodes, in combination with the Stryker RF Cannulae and Stryker MultiGen™ 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerve, and nerve roots for the relief of pain.

Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

Venom and Standard Cannulae (RF Cannulae)
The Stryker RF Cannulae, in combination with Stryker Electrodes and the Stryker RF Generator, Stryker MultiGen, or Stryker MultiGen™ 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. They are also used for selective denervation and destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerve, and nerve roots for the relief of pain.

Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

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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# SECTION

510(k) Summary

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# 510(k) Summary

## Submitter

Stryker Instruments
4100 E Milham Ave
Kalamazoo, MI 49001
(269) 389-4285

Contact Person: David Colao
Date Prepared: May 23, 2017

## Device

Name of Device: MultiGen 2 RF Generator system
Common or Usual Name: RF Generator
Classification Regulation: 882.4400 / 882.4725
Panel: Neurology
Product Code: GXD / GXI

## Predicate Devices

The following devices are predicates for the system:
Stryker RF Multi-lesion Generator (K071482)
Stryker RF Electrodes and Cannulae (K032406)
Stryker Venom Electrodes and Cannulae (K123178)

The following reference device was used in this submission:
Stryker Interventional Pain RF Generator (K032601)

## Device Description

The MultiGen™ 2 RF Generator system is a bipolar and monopolar, high frequency electrosurgical system. The MultiGen 2 RF Generator will be used in conjunction with the MultiGen 2 Splitter Cable, MultiGen 2 Electrodes, RF Cannulae, and other accessories to produce lesions by the direct application of radiofrequency currents. The generator applies temperature-controlled, radiofrequency (RF) energy into the electrode. During lesion creation, targeted nerve tissue is exposed to RF energy using an active electrode inserted into an insulated cannula with an uninsulated tip.

The application of RF energy causes a thermal reaction at the targeted nerve tissue site to create a lesion.

## Indications for Use

### Stryker MultiGen™ 2 RF Generator

The Stryker MultiGen™ 2 RF Generator, in combination with the Stryker MultiGen 2 Electrodes and RF Cannulae, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

### Venom MultiGen 2 Electrodes

The Stryker Venom MultiGen 2 Electrodes, in combination with the Stryker RF Cannulae and Stryker MultiGen™ 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerve, and nerve roots for the relief of pain.

Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

### Standard MultiGen 2 Standard Electrodes

The Stryker MultiGen 2 Electrodes, in combination with the Stryker RF Cannulae and Stryker MultiGen™ 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerve, and nerve roots for the relief of pain.

Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

### Venom and Standard Cannulae (RF Cannulae)

The Stryker RF Cannulae, in combination with Stryker Electrodes and the Stryker RF Generator, Stryker MultiGen, or Stryker MultiGen™ 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. They are also used for selective denervation and destruction

procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerve, and nerve roots for the relief of pain.

Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

## Comparison of Technological Characteristics with the Predicate Device

The predicate device is a previous generation of Stryker radiofrequency generator, the Stryker RF Multi-Lesion Generator (MultiGen). The intended uses of the subject and predicate devices are similar. The systems are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications using radiofrequency energy. Minor modifications were made to the indication for use statement to provide clarification and consistency, but do not change the meaning of the indication for use statement.

The technological characteristics of the subject and predicate devices are equivalent. Both the subject device and the primary predicate device use 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, temperature range. Both systems use the same type of accessories (a RF generator, connecting cables, electrodes, cannulae, and neutral electrode). The user interaction with the devices are similar. As demonstrated by the performance testing, the subject device has similar performance specifications as the predicate device.

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.

| FEATURE | *MultiGen™ 2 RF Generator* SUBJECT DEVICE | *Stryker RF Multi-Lesion Generator* PREDICATE DEVICE | Equivalency |
|---|---|---|---|
| **Generator** | | | |
| **510(k) Clearance** | Subject Device of Current Submission | K071482 | N/A. |
| **Indication for Use** | The Stryker MultiGen™ 2 RF Generator, in combination with the Stryker MultiGen 2 Electrodes and Cannulae are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy. | The Stryker Interventional Pain RF MultiGen, in combination with the Stryker RF Electrodes and Cannulae are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. Examples include, but are not limited to: Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy. The Stryker Interventional Pain RF MultiGen in combination with a Smith & Nephew SPINECATH™ & Acutherm™ catheters are intended for coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. | Equivalent. Indications within scope of predicate indications. |
| **Modes of Operation** | Sensory and Motor Stimulation. Pulsed and Continuous Lesioning | Sensory and Motor Stimulation. Pulsed and Continuous Lesioning | Identical. |
| **Type of Control** | Manual and Automatic | Manual and Automatic | Identical. |
| **Temperature measurement technology** | K-type thermocouple in electrode Thermocouple interface electronics in RF Generators | K-type thermocouple in electrode Thermocouple interface electronics in RF Generators | Identical. |
| **Temperature measurement location** | Distal Tip of the Nitinol Electrode | Distal Tip of the Nitinol Electrode | Identical. |
| **Temperature Range** | 37 °C - 95 °C | 37 °C - 97 °C | Equivalent. Within range of predicate. |
| **Temperature Accuracy** | 37 °C - 95 °C +-2°C | 37 °C - 95 °C +-2°C | Identical |
| **Lesion Time** | 0-999 seconds | 0-999 seconds | Identical. |

| FEATURE | *MultiGen™ 2 RF Generator*<br>**SUBJECT DEVICE** | *Stryker RF Multi-Lesion Generator*<br>**PREDICATE DEVICE** | **Equivalency** |
|---|---|---|---|
| **Stimulation Frequency** | Sensory = 50 Hz<br>Motor = 2 Hz | Sensory: 10, 20, 30, 50, 75, 100, 150, 200 (Hz)<br>Motor: 1, 2, 3, 4, 5, 7, 10, 20 (Hz) | Equivalent.<br><br>Reduce complexity. Within range of predicate. |
| **Stimulation Pulse Width** | 1 ms | .1,.2,.5,.75,1,2,3,5 (ms) | Similar.<br>Reduce complexity. Within range of predicate. |
| **Stimulation Amplitude Voltage Regulation Mode** | 0-10 V peak; accuracy + 10%, current limited to 25 mA | 0-10 V peak; accuracy + 10%, current limited to 40 mA | Equivalent. Reduction in voltage. |
| **Impedance Range** | 0-2000 ohms | 0-2000 ohms | Identical. |
| **Type of User Interface** | Touch screen graphical user interface | Touch screen graphical user interface | Identical. |
| **Type of Probe Recognition** | Automatic | Automatic | Identical. |
| **Number of Amp** | 4 | 1 | Equivalent. Simplifies control of energy. |
| **Energy delivery during multi-channel RF treatment** | Sequential non simultaneous energy delivery | Sequential non simultaneous energy delivery | Identical. |
| **Output Energy** | 0-100 watts | 0-50 watts | Equivalent.<br>The maximum current the patient is exposed to remains the same (700 mA). |
| **Output Waveform(s)** | 500kHz sinusoid | Malis Dual/Wave Waveform | Equivalent.<br>Sinusoid waveform requires lower voltage to achieve equivalent energy transfer. |
| **Monopolar/ Bipolar** | Monopolar and Bipolar | Monopolar and Bipolar | Identical. |
| **Ability to perform multiple lesions simultaneously** | Yes | Yes | Identical. |

| FEATURE | *MultiGen™ 2 RF Generator*<br>**SUBJECT DEVICE** | *Stryker RF Multi-Lesion Generator*<br>**PREDICATE DEVICE** | **Equivalency** |
|---|---|---|---|
| **Number of electrode connections** | 4 | 4 | Identical. |
| **Printer Output** | No | Yes | Equivalent.<br>Feature is not frequently used. |
| **Accessories** | • Splitter Box<br>• 3M Neutral Electrode (Ground Pad)<br>• (Neutral Electrode) Ground Pad Cable<br>• Stryker MultiGen 2 (Standard) Electrodes<br>• Stryker RF (Standard) Cannulae<br>• Venom MultiGen 2 Electrodes<br>• Venom Cannulae | • MultiGen Cable<br>• Connector Cable<br>• Hand Controller<br>• 3M Neutral Electrode (Ground Pad)<br>• (Neutral Electrode) Ground Pad Cable<br>• Stryker RF (Standard) Electrodes<br>• Stryker RF (Standard) Cannulae<br>• Venom Electrodes<br>• Venom Cannulae | Similar.<br><br>The Splitter Cable replaces the need for two MultiGen Cables or other connecting cables. |

**TABLE 1: GENERATOR COMPARISON TABLE**

| FEATURE | *Standard and Venom MultiGen 2 Electrodes*<br><br>SUBJECT DEVICE | *Standard Electrodes*<br><br>PREDICATE DEVICE | *Venom Electrodes*<br><br>PREDICATE DEVICE | Equivalency |
|---|---|---|---|---|
| **Intended Use** | | | | |
| **Electrodes** | | | | |
| **510(k) Clearance** | Subject Device | K032406 | K123178 | N/A. |
| **Indication for Use (Electrodes)** | **Standard MultiGen 2 Electrodes**<br>The Stryker MultiGen 2 Electrodes, in combination with the Stryker RF Cannulae and Stryker MultiGen 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerve, and nerve roots for the relief of pain.<br>Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.<br><br>**Venom MultiGen 2 Electrodes**<br>The Stryker Venom MultiGen 2 Electrodes, in combination with the Stryker RF Cannulae and Stryker MultiGen 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and | The Stryker RF Electrodes and Cannulae, in combination with the Stryker RF Generator, are intended for coagulation of soft tissues in orthopedic, arthroscopic, spinal, and neurosurgical applications. They are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the spinal cord, peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy. | The Stryker RF electrodes and cannulae, in combination with the Stryker RF Generator/Multigen, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy. | Equivalent.<br><br>Indications within scope of predicate indications. |

| FEATURE | *Standard and Venom MultiGen 2 Electrodes*<br><br>SUBJECT DEVICE | *Standard Electrodes*<br><br>PREDICATE DEVICE | *Venom Electrodes*<br><br>PREDICATE DEVICE | Equivalency |
|---|---|---|---|---|
| | cervical regions of the peripheral nerve, and nerve roots for the relief of pain. Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy. | | | |
| **RF Cannulae** | | | | |
| **Indication for Use (Cannulae)** | **Standard RF Cannulae / Venom RF Cannulae**<br>The Stryker RF Cannulae, in combination with Stryker Electrodes and the Stryker RF Generator, Stryker MultiGen, or Stryker MultiGen 2 RF Generator, are intended for coagulation of soft tissue in orthopedic, spinal, and neurosurgical applications. They are also used for selective denervation and destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerve, and nerve roots for the relief of pain.<br>Examples include, but are not limited to: Facet Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy. | The Stryker RF Electrodes and Cannulae, in combination with the Stryker RF Generator, are intended for coagulation of soft tissues in orthopedic, arthroscopic, spinal, and neurosurgical applications. They are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the spinal cord, peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Percutaneous Chordotomy/Dorsal Root Entry Zone (DREZ) Lesion, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy. | The Stryker RF electrodes and cannulae, in combination with the Stryker RF Generator/Multigen, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy. | Equivalent.<br><br>Indications within scope of predicate indications. |

| FEATURE | *Standard and Venom MultiGen 2 Electrodes*<br>SUBJECT DEVICE | *Standard Electrodes*<br>PREDICATE DEVICE | *Venom Electrodes*<br>PREDICATE DEVICE | Equivalency |
|---|---|---|---|---|
| **Technological Indications** | | | | |
| **Electrodes** | | | | |
| **Electrode Lengths** | **Standard**<br>50mm, 100mm, 150mm, 200mm<br>**Venom**<br>100mm, 150mm | 50mm, 100mm, 150mm, | 100mm, 150mm | Equivalent. Additional length. |
| **Nitinol Electrode Radial Dimensions** | **Standard**<br>Inside Diameter: 0.25mm<br>Outside Diameter: 0.40mm<br>**Venom**<br>Inside Diameter: 0.25mm<br>Outside Diameter: 0.50mm | Inside Diameter: 0.25mm<br>Outside Diameter: 0.40mm | Inside Diameter: 0.25mm<br>Outside Diameter: 0.50mm | Identical. |
| **Design** | **Standard**<br>27 gauge (0.4mm OD) Nitinol electrode<br>PEEK electrode hub<br>4 conductor silicone cable (approximately 5 feet long)<br>K-type thermocouple<br>ODU cable connector assembly (diameter: 8.9mm, length 34.9 mm)<br><br>**Venom**<br>25 gauge (0.5mm OD) Nitinol electrode<br>PEEK electrode hub<br>4 conductor silicone cable (approximately 5 feet long)<br>K-type thermocouple<br>ODU cable connector assembly (diameter: 8.9mm, length 34.9 mm) | 27 gauge (0.4mm OD) Nitinol electrode<br>PEEK electrode hub<br>4 conductor silicone cable (approximately 4 feet long)<br>K-type thermocouple<br>ODU cable connector assembly (diameter: 13.9mm, length 47.5 mm) | 25 gauge (0.5mm OD) Nitinol electrode<br>PEEK electrode hub<br>4 conductor silicone cable (approximately 4 feet long)<br>K-type thermocouple<br>(diameter: 13.9mm, length 47.5 mm) | Equivalent. |

| FEATURE | *Standard and Venom MultiGen 2 Electrodes*<br><br>**SUBJECT DEVICE** | *Standard Electrodes*<br><br>**PREDICATE DEVICE** | *Venom Electrodes*<br><br>**PREDICATE DEVICE** | Equivalency |
|---|---|---|---|---|
| **Temperature Measurement Technology** | K-type thermocouple in electrode<br><br>Thermocouple interface electronics in RF Generators | K-type thermocouple in electrode<br><br>Thermocouple interface electronics in RF Generators | K-type thermocouple in electrode<br><br>Thermocouple interface electronics in RF Generators | Identical. |
| **Temperature Measurement Location** | Distal Tip of the Electrode | Distal Tip of the Electrode | Distal Tip of the Electrode | Identical. |
| **Sterility** | Steam or Vaporized Hydrogen Peroxide | Steam | Steam | Equivalent. |
| **Materials** | Nitinol<br>Silicone Rubber<br>PEEK(Polyether ether ketone)<br>Stainless Steel | Nitinol<br>Silicone Rubber<br>PEEK(Polyether ether ketone)<br>Stainless Steel | Nitinol<br>Silicone Rubber<br>PEEK(Polyether ether ketone)<br>Stainless Steel | Identical. |
| **Cannulae** | | | | |
| **Sizes** | **Lengths**<br>**Standard**<br>50mm, 100mm, 150mm, 200mm<br>**Venom**<br>100mm, 150mm<br><br>**Diameters**<br>**Standard**<br>18G, 20G, 22G<br>**Venom**<br>18G, 20G,<br><br>**Active Tip**<br>**Standard**<br>5.0mm, 7.5mm, 10.0mm, 15.0mm<br>**Venom**<br>10mm | **Lengths**<br>50mm, 100mm, 150mm<br><br>**Diameters**<br>20G, 22G<br><br>**Active Tip**<br>2.5mm, 4.0mm, 5.0mm, 7.5mm, 10.0mm, 15.0mm | **Lengths**<br>100mm, 150mm<br><br>**Diameters**<br>18G, 20G<br><br>**Active Tip**<br>10mm | Equivalent.<br><br>Longer Length. Gages and Active Tips within cleared range. |

| FEATURE | *Standard and Venom MultiGen 2 Electrodes*<br><br>SUBJECT DEVICE | *Standard Electrodes*<br><br>PREDICATE DEVICE | *Venom Electrodes*<br><br>PREDICATE DEVICE | Equivalency |
|---|---|---|---|---|
| **Design** | **Standard**<br>The Standard RF Cannula consists of 18, 20 or 22 gauge stainless steel tubing cut to length. A bevel tip is created via an electro-chemical grinding process. The cannula is insulated with siliconised polyester. A polycarbonate cannula hub with inert black ink marking is attached to the proximal end.<br><br>**Venom**<br>The Venom™ Cannula consists of 18 or 20 gauge stainless steel tubing cut to length. A bevel tip and a side port are created at the distal end via an electro-chemical grinding process. The cannula is insulated with siliconised polyester. A polycarbonate cannula hub with inert black ink marking is attached to the proximal end. | The Standard RF Cannula consists of 20 or 22 gauge stainless steel tubing cut to length. A bevel tip is created via an electro-chemical grinding process. The cannula is insulated with siliconised polyester. Additionally the cannulae include a small amount of liquid silicone. A polycarbonate cannula hub with inert black ink marking is attached to the proximal end. | The Venom™ Cannula consists of 18 or 20 gauge stainless steel tubing cut to length. A bevel tip and a side port are created at the distal end via an electro-chemical grinding process. The cannula is insulated with siliconised polyester. A polycarbonate cannula hub with inert black ink marking is attached to the proximal end. | Equivalent. |
| **Sterility** | EtO | EtO | EtO | Identical. |
| **Materials** | Stainless Steel<br>Siliconised Polyester<br>Polycarbonate plastic<br>Inert black ink<br>Polyethylene | Stainless Steel<br>Siliconised Polyester<br>Liquid Silicone<br>Polycarbonate plastic<br>Inert black ink<br>Polyethylene | Stainless Steel<br>Siliconised Polyester<br>Polycarbonate plastic<br>Inert black ink<br>Polyethylene | Equivalent. |

**TABLE 2: ELECTRODE AND CANNULA COMPARISON TABLE**

## Performance Data

The following performance data were provided in support of the substantial equivalence decision:

### Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing were conducted on the subject device in accordance with the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012 (IEC 60601-1:2005, mod).
- IEC 60601-2-2 Edition 5.0 2009-02 [including: technical corrigendum 1 (2014)]
- IEC 60601-1-2 Edition 3: 2007-03 and
- IEC 60601-1-2 Edition 4.0 2014-02

### Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

### Performance Testing – Bench

The following design verification activities have been performed to ensure the correct functionality of the system as it has been specified:

- Substantial equivalence testing verifying the radiofrequency ablations created by the subject device are equivalent to the radiofrequency ablations created by the predicate device.
- Multi-Lesion testing verifying that the MultiGen 2 RF Generator system functions properly with all possible set ups and procedural variations.
- MultiGen 2 Splitter Cable (Splitter Cable) life testing.
- MultiGen 2 Electrode NOVRAM testing showing that the NOVRAM meets specifications.
- MultiGen 2 RF Generator current limitation testing.

### Animal Study

No animal studies were performed to support substantial equivalence.

### Clinical Studies

No clinical studies were performed to support substantial equivalence.

## Conclusions

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.