December 22, 2020

Avanos Medical, Inc.
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K203066
Trade/Device Name: COOLIEF Cooled Radiofrequency Kit Advanced
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: December 16, 2020
Received: December 17, 2020

Dear Rafael Aguila:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K203066

Device Name

COOLIEF* Cooled Radiofrequency Kit Advanced

Indications for Use *(Describe)*

The COOLIEF* Cooled Radiofrequency Kit Advanced is to be used in conjunction with the Radiofrequency (RF) Pain Management Generator (PMG-ADVANCED) or the COOLIEF* Radiofrequency Generator (CRG-Advanced) to create lesions in nervous tissue. The device includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target site. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥50% reduction in pain) to a diagnostic genicular nerve block.

The COOLIEF* SINERGY* Cooled Radiofrequency Kit Advanced is to be used in conjunction with the Radiofrequency (RF) Pain Management Generator (PMG-ADV ANCED) or the COOLIEF* Radiofrequency Generator (CRG-ADVAN CED) to create RF lesions in nervous tissue. The device includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target 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.**

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

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# 510(k) Summary

**Date: December 22, 2020**

**Submission Number: K203066**

**Manufacturer / Sponsor Name, Address, Telephone, Contact Information**

| | |
|---|---|
| **510(k) Manufacturer / Address** | Avanos Health, Inc.<br>5405 Windward Parkway<br>Alpharetta, GA 30004 |
| **Contact Person** | Christian Supina<br>Associate Director, Regulatory Affairs<br>Phone: (470) 462-8137 |

**Classification, Common Name, Device Name**

| | |
|---|---|
| **Trade Name** | COOLIEF* Cooled Radiofrequency Kit Advanced;<br>COOLIEF* SINERGY* Cooled Radiofrequency Kit Advanced |
| **Common Name** | Radiofrequency Lesion Probe |
| **Classification Name** | Probe, Radiofrequency lesion |
| **Regulation Number** | 21 CFR §882.4725 |
| **Product Code** | GXI |
| **Device Classification** | II |
| **Review Panel** | (84) Neurology |
| **Reason for Premarket Notification** | Modification to predicate device. The probe and fluid tubing kit are part of the COOLIEF* Cooled Radiofrequency Kit Advanced |
| **Prior Submission** | There are no previous submissions for this change. |

**Primary Predicate Device:**

| | |
|---|---|
| Trade Name | COOLIEF* Cooled Radiofrequency Probe |
| 510(k) Number | K163461 |
| Manufacturer | Halyard Health, Inc. (currently Avanos Medical, Inc.) |
| Common Name | Radiofrequency lesion probe |
| Classification Name | Probe, Radiofrequency Lesion |
| Regulation Section | 21 CFR 882.4725 |
| Device Classification | II |
| Product Code | GXI |
| Review Panel | (84) Neurology |

**Secondary Predicate Device:**

| | |
|---|---|
| Trade Name | COOLIEF* Cooled Radiofrequency Kit |
| 510(k) Number | K163236 |
| Manufacturer | Halyard Health, Inc. (currently Avanos Medical, Inc.) |
| Common Name | Radiofrequency lesion probe |
| Classification Name | Probe, Radiofrequency Lesion |
| Regulation Section | 21 CFR 882.4725 |
| Device Classification | II |
| Product Code | GXI |
| Review Panel | (84) Neurology |

**Description of the Device:**
The COOLIEF* Cooled Radiofrequency Kit Advanced is a modification to the predicate COOLIEF* Cooled Radiofrequency Kit cleared under K163461. The subject device consists of the following:

- COOLIEF* Cooled Radiofrequency Probe Advanced
- COOLIEF* Cooled Radiofrequency Fluid Tubing Kit
- COOLIEF* Cooled Radiofrequency Fluid Delivery Introducer

The modifications to the subject device are specific to the probe and fluid tubing kit.

The subject probe and fluid tubing kit are also included in the COOLIEF*SINERGY* Cooled Radiofrequency Kit Advanced. The following shows the general naming convention used for the COOLIEF* Cooled RF Kits, and how this relates to specific product characteristics.

**COOLIEF* Cooled Radiofrequency Probe Advanced**

- CRPA-17-XXX; where 17 is the gauge size for mating to introducer, XXX is the length in mm (50, 75, 100, 150 mm)
- CRPA designates "Cooled Radiofrequency Probe Advanced"

**COOLIEF* Cooled Radiofrequency Kit Advanced**

- CRKA-17-XXX-##; where 17 is the gauge size, XXX is the length in mm (50, 75, 100, or 150 mm), and ## is the active tip length in mm (2, 4, or 5.5 mm)
- CRKA designates "Cooled Radiofrequency Kit Advanced

**COOLIEF* Multi-Cooled Radiofrequency Kit Advanced**

- MCKAY-17-XXX-##; where Y indicates number of probes supplied with the kit (2 or 3), 17 is the gauge size, XXX is the length in mm (50, 75, 100, 150), and ## is the active tip length in mm (2, 4, or 5.5 mm)
- MCKA designates "Multi-Cooled Kit Advanced"

**COOLIEF* SINERGY* Cooled Radiofrequency Kit Advanced**

- SIKA-17-XXX-4; where 17 is the gauge size, XXX is the length in mm (75 or 150 mm)
- SIKA designates "SINERGY* Kit Advanced"

The subject device has several configurations based on the anatomic region of use, length of the introducer and probe, and the length of the active electrode. The COOLIEF* Cooled Radiofrequency Kit Advanced is composed of fluid delivery introducers, probes, and fluid tubing kit. The kit is sterile, non-pyrogenic, and single-use. The COOLIEF* Cooled Radiofrequency Kit Advanced is to be used in conjunction with the Radiofrequency (RF) Pain Management Generator (PMG-ADVANCED) or the COOLIEF* Radiofrequency Generator (CRG-Advanced) to create lesions in nervous tissue. The system devices for the PMG and CRG systems are shown in Table 1

**Table 1.** COOLIEF* Generator System Devices (PMG and CRG)

| COOLIEF* System Reference | Device Description | Principle of Operation | Condition of Use | 510(k) Reference |
|---|---|---|---|---|
| Pain Management Generator System (compatible with subject COOLIEF* Cooled RF Kit Advanced) | Pain Management Generator (PMG) | Source of RF energy | Clinical Use by trained physician | K072478 |
| | Peristaltic Pump (PPU) | Circulates cooling water or saline to probe tip in a closed-loop | Clinical Use by trained physician | K031951 |
| | Fluid Delivery Introducer | Provides a path for the probe to the nervous tissue and includes a fluid delivery system | Clinical Use by trained physician | K163236 |
| | Dispersive Electrode / Grounding Pad | Completes electrical circuit | Clinical Use by trained physician | K140658 |
| | Therapy / Connector Cables | Connects probes to generator (electrical) | Clinical Use by trained physician | K072478 |
| COOLIEF* Radiofrequency Generator System (compatible with subject COOLIEF* Cooled RF Kit Advanced) | COOLIEF* Radiofrequency Generator (CRG) | Source of RF energy | Clinical Use by trained physician | K192491 |
| | Quad Pump Unit (QPU) | Circulates cooling water or saline to probe tip in a closed-loop | Clinical Use by trained physician | K192491 |
| | Fluid Delivery Introducer | Provides a path for the probe to the nervous tissue and includes a fluid delivery system | Clinical Use by trained physician | K163236 |
| | Dispersive Electrode / Grounding Pad | Completes electrical circuit | Clinical Use by trained physician | K140658 |
| | Therapy / Connector Cables | Connects probes to generator (electrical) | Clinical Use by trained physician | K192491 |

The COOLIEF* SINERGY* Cooled Radiofrequency Kit Advanced is to be used in conjunction with the Radiofrequency (RF) Pain Management Generator (PMG-ADVANCED) or the COOLIEF* Radiofrequency Generator (CRG-ADVANCED) to create RF lesions in nervous tissue. This device includes the same components as the COOLIEF* Cooled RF Kit Advanced, but also includes an Epsilon Ruler. The Epsilon Ruler is a circular stainless-steel ruler that may be used during the COOLIEF SINERGY* procedure to assist the user in providing a 'template' around the foramen, which is specific to performing procedure around the sacroiliac (SI) nerve.

**Indications for Use:**

The COOLIEF* Cooled Radiofrequency Kit Advanced is to be used in conjunction with the Radiofrequency (RF) Pain Management Generator (PMG-ADVANCED) or the COOLIEF* Radiofrequency Generator (CRG-Advanced) to create lesions in nervous tissue. The device includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target site. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥50% reduction in pain) to a diagnostic genicular nerve block.

The COOLIEF* SINERGY* Cooled Radiofrequency Kit Advanced is to be used in conjunction with the Radiofrequency (RF) Pain Management Generator (PMG-ADVANCED) or the COOLIEF* Radiofrequency Generator (CRG-ADVANCED) to create RF lesions in nervous tissue. The device includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target site.

**Table 2.** Indications for Use – Comparison of Subject Device, Primary and Secondary Predicate Devices

| Subject COOLIEF* Cooled Radiofrequency Kit Advanced | Primary Predicate COOLIEF* Cooled Radiofrequency Kit | Secondary Predicate COOLIEF* Cooled Radiofrequency Kit |
|---|---|---|
| 510(k) number K203066 | K163461 | K163236 |
| The COOLIEF* Cooled Radiofrequency Kit Advanced is to be used in conjunction with the Radiofrequency (RF) Pain Management Generator (PMG-ADVANCED) or the COOLIEF* Radiofrequency Generator (CRG-Advanced) to create lesions in nervous tissue. The device includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target site. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥50% reduction in pain) to a diagnostic genicular nerve block. The COOLIEF* SINERGY* Cooled Radiofrequency Kit Advanced is to be used in conjunction with the Radiofrequency (RF) Pain Management Generator (PMG-ADVANCED) or the COOLIEF* Radiofrequency Generator (CRG-ADVANCED) to create RF lesions in nervous tissue. The device includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target site. | The COOLIEF* Radiofrequency Kit is to be used in conjunction with the radiofrequency generator to create lesions in nervous tissue. The device includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target site. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥50% reduction in pain) to a diagnostic genicular nerve block. | The HALYARD* COOLIEF* Cooled Radiofrequency Kit, in combination with the HALYARD* Radiofrequency (RF) Generator (PMG-BASIC/PMG-ADVANCED) (formerly Baylis Pain Management Generator or KIMBERLY-CLARK® Pain Management Generator) is intended for the creation of Radio-Frequency (RF) heat lesions in nervous tissue for the relief of pain, and includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target site. |

The COOLIEF* Cooled Radiofrequency Kit cleared under K163236 (Halyard Health, currently Avanos Medical) is included as a secondary predicate for this submission as it consists of the same COOLIEF* Cooled RF Kit devices as the predicate device (K163461), and includes the following indications for use for the COOLIEF* SINERGY* Cooled RF Kit:

> *The HALYARD* COOLIEF* SINERGY* Cooled Radiofrequency Kit, in combination with the HALYARD* Radiofrequency (RF) Generator (PMG-BASIC/PMG-ADVANCED) (formerly Baylis Pain Management Generator or KIMBERLY-CLARK® Pain Management Generator) is intended for the creation of Radio-Frequency (RF) heat lesions in nervous tissue for the relief of pain, and includes a fluid delivery system for commonly used fluid agents limited to contrast medium, saline, and/or anesthetic solution delivery at the target site.*

The proposed indications for use for the subject COOLIEF* SINERGY* Cooled RF Kit Advanced are equivalent to the secondary predicate device (K163226). The proposed indications for use for the subject device include references for use with both the Pain Management Generator (PMG-ADVANCED) and the COOLIEF* Radiofrequency Generator (CRG-Advanced), as the COOLIEF* Cooled Radiofrequency Probe Advanced is compatible with both generator systems. The COOLIEF* Radiofrequency Generator system was recently cleared under K192491 (Avanos Medical, Inc.), and testing has been completed to demonstrate the safe and effective use with the subject COOLIEF* Cooled Radiofrequency Kit Advanced.

The intended use for the subject and predicate devices is the same, and therefore do not raise any issues related to safety or effectiveness.

**Comparison of Technological Characteristics of the Predicate and Proposed Device:**

The technological characteristics, indications for use, and construction material of the COOLIEF* Radiofrequency Kit Advanced (subject device) are substantially equivalent to the currently-marketed predicate device COOLIEF* Cooled Radiofrequency Probe, cleared under K163461. The same fundamental technology, assembly, labeling, packaging, and sterilization method is used.

The COOLIEF* Cooled RF Probe Advanced (CRPA probe) adds a new smaller, lighter handle compared to the COOLIEF* Cooled RF Probe (CRP probe) handle. The new handle is lighter than the predicate device probe handle, which is used to direct the positioning of the probe during the procedure. In addition, the new handle incorporates a 90-degree design, which makes the probe less top-heavy by directing the cables and fluid tubing at a 90-degree angle from the probe shaft. These changes were made to the probe to improve the overall handling of the probe during the RF procedure.

The probe utilizes more flexible fluid tubing than the predicate device, allowing the user to more easily maneuver it during the COOLIEF* Radiofrequency procedure. The fluid tubing is thermally bonded to the jacket of the electrical cable to further improve probe handling and management during the procedure. The material of the probe fluid lines is the same as the predicate device (polyvinyl chloride). Reference Figure 1 for a picture and illustration of the CRPA probe.

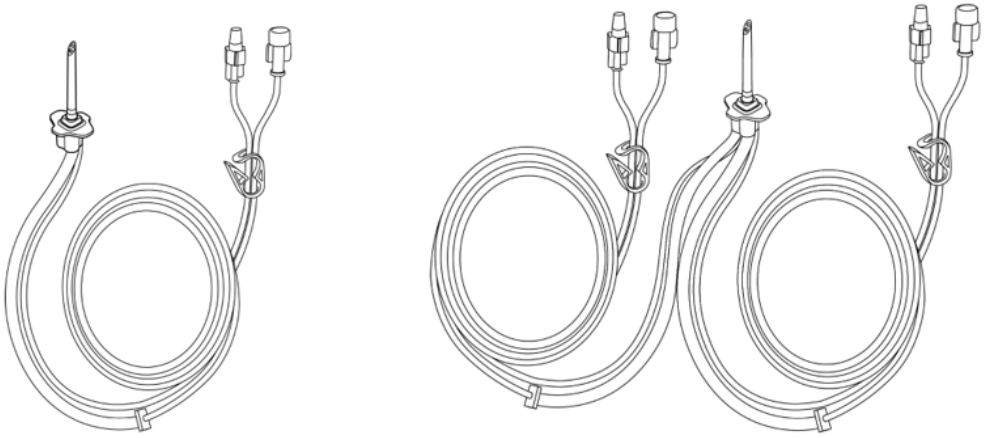
The subject device fluid tubing kit includes a dual lumen IV spike for accessing standard IV bags to be used as the cooling fluid reservoir. The IV spike on the fluid tubing kit will allow the user to more easily access water or saline for use during the procedure set-up, instead of having the fill a burette with water (predicate).

The IV spike on the subject device is the same material as the burette (polycarbonate). The fluid tubing kit also uses more flexible tubing than the predicate device for easier maneuverability during use and is the same material as the predicate tubing (PVC). This updated fluid tubing kit configuration continues to support closed-loop cooling fluid recirculation, same as the predicate device. The peristaltic tubing that is loaded into the peristaltic pump heads for fluid circulation is now tinted blue in color to help the user distinguish it from the other sections of the fluid tubing. There was no color for the predicate tubing. Reference Figure 2 for an illustration of the Fluid Tubing Kit (single and dual).

Tables 3 and 4 provide a comparison of similarities and differences between the subject and predicate devices. These tables include probes and fluid tubing kits from both COOLIEF* Cooled RF Kits and COOLIEF* SINERGY* kits.

Figure 1. Picture of COOLIEF* Cooled Radiofrequency Probe Advanced

Figure 2. Illustration of COOLIEF* Radiofrequency Tubing Kit



CRA-TBK-1 (Single-Probe Configuration)

CRA-TBK-2 (Dual-Probe Configuration)

**Table 3.** Similarities in Characteristics between Subject Device, Primary Predicate Device, and Secondary Predicate Device

| Characteristics | Subject Device COOLIEF* Cooled Radiofrequency Kit Advanced (K203066) | Primary Predicate Device COOLIEF* Cooled RF Probe (K163461) | Secondary Predicate Device COOLIEF* Cooled RF Kit (K163236) |
|---|---|---|---|
| Operating Principle | Cooled Radiofrequency Ablation | Cooled Radiofrequency Ablation | Cooled Radiofrequency Ablation |
| Cooling Method | Closed-loop circulation of cooling fluid to the tip of the active electrode using a peristaltic pump | Closed-loop circulation of cooling fluid to the tip of the active electrode using a peristaltic pump | Closed-loop circulation of cooling fluid to the tip of the active electrode using a peristaltic pump |
| Temperature Measurement Device | Modified Type-T thermocouple | Modified Type-T thermocouple | Modified Type-T thermocouple |
| Temperature Measurement Location | Distal tip of active electrode | Distal tip of active electrode | Distal tip of active electrode |
| Temperature Measurement Range | 38°C – 95°C | 38°C – 95°C | 38°C – 95°C |
| Temperature Accuracy | ± 3°C | ± 3°C | ± 3°C |
| Probe Shaft Length | 50mm, 75mm, 100mm, 150mm | 50mm, 75mm, 100mm, 150mm | 50mm, 75mm, 100mm, 150mm |
| Active Electrode Length | 2mm, 4mm, 5.5mm | 2mm, 4mm, 5.5mm | 2mm, 4mm, 5.5mm |
| Single Use | Yes | Yes | Yes |
| Sterility | Sterilized by Ethylene Oxide (SAL = $10^{-6}$) | Sterilized by Ethylene Oxide (SAL = $10^{-6}$) | Sterilized by Ethylene Oxide (SAL = $10^{-6}$) |
| Fluid Lines | Material: PVC<br>Dual Lumen | Material: PVC<br>Dual Lumen | Material: PVC<br>Dual Lumen |
| Luer Lock Connector | Female Luer Lock Connector: transparent Polycarbonate (PC)<br>Male Luer Lock Connector: transparent PC | Female Luer Lock Connector: transparent Polycarbonate (PC)<br>Male Luer Lock Connector: transparent PC | Female Luer Lock Connector: transparent Polycarbonate (PC)<br>Male Luer Lock Connector: transparent PC |
| Luer Caps | Vented Female Luer Cap: white polypropylene<br>Vented Male Luer Cap: white Nylon | Vented Female Luer Cap: white polypropylene<br>Vented Male Luer Cap: white Nylon | Vented Female Luer Cap: white polypropylene<br>Vented Male Luer Cap: white Nylon |

**Table 4.** Differences in Characteristics between Subject Device, Primary Predicate Device, and Secondary Predicate Device

| Characteristic | Subject Device COOLIEF* Cooled Radiofrequency Kit Advanced (K203066) | Primary Predicate Device COOLIEF* Cooled RF Probe (K163461) | Secondary Predicate Device COOLIEF* Cooled RF Kit (K163236) |
|---|---|---|---|
| Probe Handle Shape | L-shaped (90° between probe shaft and cable/tubing) | Cylindrical (probe shaft and cable/tubing in-line) | Cylindrical (probe shaft and cable/tubing in-line) |
| Probe Handle Material | Material: Polycarbonate<br>Color: White | Material: Acetal<br>Color: Black | Material: Acetal<br>Color: Black |
| Tubing/Cable Management | Fluid tubing is thermally bonded to cable | Fluid tubing is not bonded cable | Fluid tubing is not bonded cable |
| Cable Jacket | Jacket Material: Medical Grade PVC | Jacket Material: Silicone | Jacket Material: Silicone |
| Fluid Management Kit Operation | Spike on tubing kit connected to standard IV bag (saline or sterile water) prior to procedure | Burette on tubing kit filled with sterile water prior to procedure | Burette on tubing kit filled with sterile water prior to procedure |
| Peristaltic Tubing | Material: Polyvinyl Chloride (PVC)<br>Color: Tinted Blue | Material: Tygon E-LFL<br>Color: Transparent | Material: Tygon E-LFL<br>Color: Transparent |
| Fluid Reservoir and Connection | 250 – 1000mL standard IV bags filled with saline or sterile water (not provided with kit)<br>IV spike (polycarbonate) bonded to fluid tubing | 70mL burettes filled with sterile water<br>Burettes (polycarbonate) bonded to fluid tubing | 70mL burettes filled with sterile water<br>Burettes (polycarbonate) bonded to fluid tubing |

**Summary of Non-Clinical Testing (Performance Testing)**

Performance Testing for the subject device was conducted in conjunction with both the Pain Management Generator (PMG) and COOLIEF* Radiofrequency Generator (CRG) Pain Management Systems. The bench performance testing demonstrates that the subject device performs as intended. As a result of the change to the probe and fluid tubing, no new risks were identified, and the device functions as intended. Table 5 provides a summary of non-clinical testing.

**Table 5. Summary of Non-Clinical Testing (Performance Testing)**

| Test Name / Description | Result |
|---|---|
| <u>Sterilization and Shelf-Life</u><br>• **ANSI/AAMI/ISO 11135:2014**, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* | Pass |
| <u>Bacterial Endotoxins Testing</u> | Pass |

| Test Name / Description | Result |
|---|---|
| • **ST72:2019**, *Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing* | |
| Human Factors<br>• **62366-1:2015**, *Medical devices - Application of usability engineering to medical devices* | Pass |
| Biocompatibility<br>• **10993-5: 2009**, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*<br>• **10993-10: 2010**, *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*<br>• **10993-11: 2006**, *Tests for Acute Systemic Toxicity and Material-Mediated Pyrogenicity* | Pass |
| Electromagnetic Compatibility and Electrical Safety (for probe)<br>• **60601-1:2005+AM1 (2012),** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>• **60601-1-6: 2010+A1:2013**, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability<br>• **60601-1-9:2013**, Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design<br>• **60601-2-2:2017**, Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories | Pass |
| Performance Verification<br>• Lesion Size Testing<br>• Probe Thermocouple Accuracy Testing<br>• Probe Fluid Delivery Port Injection Force Testing<br>• Flow Rate Testing<br>• High Pressure Leak Testing | Pass |

| Test Name / Description | Result |
|---|---|
| • Probe Mass Testing<br>• Structural Strength Testing<br>• Sterile Water and Saline Cooling Fluids Testing<br>• Packaging Verification (**ANSI/AAMI/ISO 11607-1:2019**, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems*) | |

**Clinical Performance Data:**

Clinical data was not applicable for the subject device.

**Conclusions**

It has been established that the subject device is substantially equivalent to the predicate devices cleared under 510(k) K163461 and K163236 in terms of indications for use, technology, and performance specifications. The non-clinical testing performed on the subject device demonstrates that the design changes made to the probe and fluid tubing kit do not raise any new issues or questions on the safety or effectiveness of the device.