February 21, 2020

Avanos Medical, Inc.
Thomas Kozma, Ph.D.
Director, Regulatory Affairs
5405 Windward Parkway
Alpharetta, Georgia 30004

Re: K192491
Trade/Device Name: COOLIEF* Radiofrequency Generator (CRG) System
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD
Dated: January 20, 2020
Received: January 22, 2020

Dear Dr. Thomas Kozma:

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,

Xiaolin Zheng, Ph.D., M.S.
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)*
K192491

Device Name

COOLIEF* Radiofrequency Generator (CRG) System

Indications for Use *(Describe)*

COOLIEF* Radiofrequency Generator (CRG) System is indicated for use to create lesions during neurological lesion procedures and for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. The CRG is to be used with only Avanos RF Probes and accessories, such as Avanos TransDiscal Probes, COOLIEF*/Standard RF Pain Management Probes, Cannulas, Introducers, and Fluid Delivery Introducers. Use of CRG System is limited to the indications cleared under these Avanos devices and accessories.

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

MANUFACTURER/SPONSOR NAME, ADDRESS, TELEPHONE, CONTACT INFORMATION

Date Summary Prepared	February 18, 2020
510(k) Manufacturer/ Sponsor Address	Avanos Medical, Inc. 5405 Windward Parkway Alpharetta, GA 30004
Contact Person	Thomas Kozma, PhD Director, Regulatory Affairs Phone: (470) 448-5681

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Trade Name	COOLIEF* Radiofrequency Generator (CRG) System
Common Name	Lesion Radiofrequency Generator
Classification Name	Generator, Lesion, Radiofrequency
Regulation Number	21 CFR § 882.4400
Product Code	GXD
Device Classification	II

PREDICATE DEVICES

Manufacturer Name	Predicate Device Trade Name	510(k) Number
Baylis Medical Company (Currently Owned by Avanos Medical, Inc.)	Baylis Pain Management Generator – TD	K072478

DEVICE DESCRIPTION

The COOLIEF* Radiofrequency Generator (CRG) System uses controlled radiofrequency energy to generate heat that is used to create lesions in neurological tissues or to coagulate and decompress disc material to treat symptomatic patients with contained herniated discs. The following components of the predicate Pain Management Generator-TD (K072478), which must be used together, have been modified and are the subject of this 510(k): a) COOLIEF* Radiofrequency Generator (CRG), b) COOLIEF* Quad Pump Unit (QPU), and c) COOLIEF* Therapy Cables.

a) COOLIEF* Radiofrequency Generator (CRG):
CRG is an 80-watt Radio-Frequency (RF) Generator with four independent RF channels, allowing all RF channels to be activated individually or altogether. The system is controlled via a touch-screen interface display that includes user controls, alarm messages, and on-screen selection of lesioning modalities. Like the predicate Pain Management Generator device (K072478), the CRG can operate in six treatment modes that include: Standard RF, Pulsed RF, Bipolar RF, Cooled RF, TransDiscal Monopolar RF, and TransDiscal Bipolar RF. The CRG can only be used with the other subject devices components of the COOLIEF* Radiofrequency Generator System (i.e the QPU and Therapy Cables).

b) COOLIEF* Quad Pump Unit (QPU):
COOLIEF* QPU pump heads circulate fluid within a closed-loop system, using Avanos-marketed COOLIEF* fluid tubing kits, to cool the tip region of the COOLIEF* RF Probes. The QPU has four peristaltic pump heads that rotate to drive the fluid flow. The COOLIEF* QPU is controlled by the CRG and can be used with only components of the COOLIEF* Radiofrequency Generator System.

c) COOLIEF* Therapy Cables:
COOLIEF* Therapy Cables are provided in the following three configurations for use with only the CRG:

1. COOLIEF* Multi-RF Therapy Cable is used for Standard, Pulsed, or Biopolar RF treatment modes. The cable is re-usable and not intended to be in the sterile field.
2. COOLIEF* Multi-Cooled RF Therapy Cable is used for Cooled RF treatment mode. The cable is re-usable and not intended to be in the sterile field.
3. COOLIEF* TransDiscal* Y-Connector Therapy Cable is used for the TransDiscal Monopolar or TransDiscal Bipolar RF treatment modes. The cable is re-usable and not intended to be in the sterile field.

Each configuration of the COOLIEF* cable is compatible with only the CRG.

The subject device components of the COOLIEF* Radiofrequency Generator System can be used with the following additional COOLIEF* components that have been previously cleared: RF Probe Electrodes (i.e., Standard, TransDiscal, or Cooled) (K002389, K031951, and K163461), Cannula/Introducers (K972846, K031951, and K163236), Fluid Tubing Kit (K031951), and Split Grounding Pad (K140658).

INDICATIONS FOR USE

COOLIEF* Radiofrequency Generator (CRG) System is indicated for use to create lesions during neurological lesion procedures and for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. The CRG is to be used with only Avanos RF Probes and accessories, such as Avanos TransDiscal Probes, COOLIEF*/Standard RF Pain Management Probes, Cannulas, Introducers, and Fluid Delivery Introducers. Use of CRG System is limited to the indications cleared under these Avanos devices and accessories.

COMPARISON OF SUBJECT DEVICE TO PREDICATE DEVICE

Like the predicate devices, the Generator, Quad Pump, and Therapy Cable are used outside of the sterile field and are reusable. The COOLIEF* Radiofrequency Generator (CRG) System is used in a clinical setting, such as an outpatient surgery center or operating room in a hospital by licensed healthcare professionals with access to fluoroscopic or ultrasound imaging. The following table compares the general and technological characteristics of the subject CRG System and predicate device (i.e., Baylis Pain Management Generator - TD (K072478) that must be used together to achieve intended use).

COOLIEF* Radiofrequency Generator (CRG)			
	Subject Device - CRG	**Predicate Device - PMG**	**Comment**
Device Name (510(k))	COOLIEF* Radiofrequency Generator (CRG) System (RF Generator, Peristaltic Pump, and Therapy Cables) (K192491)	Baylis Pain Management Generator–TD (RF Generator) (K072478)	RF Generator, Peristaltic Pump, and Therapy Cables must be used together to achieve intended use.
Regulation	21 CFR § 882.4400	21 CFR § 882.4400	Same as Predicate Device
Product Code	GXD – RF Lesion Generator	GXD - RF Lesion Generator	Same as Predicate Device

COOLIEF* Radiofrequency Generator (CRG)			
	Subject Device - CRG	**Predicate Device - PMG**	**Comment**
Indications for Use	COOLIEF* Radiofrequency Generator (CRG) System is indicated for use to create lesions during neurological lesion procedures and for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. The CRG is to be used with only Avanos RF Probes and accessories, such as Avanos TransDiscal Probes, COOLIEF*/Standard RF Pain Management Probes, Cannulas, Introducers, and Fluid Delivery Introducers. Use of CRG System is limited to the indications cleared under these Avanos devices and accessories.	Baylis Pain Management Generator is indicated for use to create lesions during neurological lesion procedures, and for the coagulation and decompression of disc material to treat symptomatic patient with contained herniated discs. The Baylis PMG-TD is to be used with separately approved probes such as Baylis TransDiscal Probe, Oratec Spinecath™ and Baylis Pain Management Probes.	Same as Predicate Device, except for: Updated branding from Baylis to Avanos COOLIEF and specified use to only Avanos probes and accessories, and indications limited to these Avanos probes and Accessories. This branding change has no impact on performance or safety.
Prescriptive Status	Rx Only	Rx Only	Same as Predicate Device
Environment of Use	Clinical setting with licensed professional	Clinical setting with licensed professional	Same as Predicate Device
AC Power Compatibility	100-120V, 220-240V	100-120V, 220-240V	Same as Predicate Device
Energy Delivery	Radiofrequency at 460kHz +/- 1%, Quasi-sinusoidal	Radiofrequency at 460kHz +/- 1%, Quasi-sinusoidal	Same as Predicate Device
Generator Max Power	80 Watts	50 Watts	Equivalent to Predicate Device Subject device has greater max power capacity, but max power per probe is equivalent at 50 W (see row below); therefore, no negative impact on performance or safety.
Max Power (Current) per Probe	50 Watts (900mA)	50 Watts (900mA)	Same as Predicate Device
Stimulation Frequency	Sensory = 50 Hz Motor = 2Hz	Sensory = 50 Hz Motor = 2Hz	Same as Predicate Device
Stimulation Pulse Width	0.1, 0.2, 0.5, and 1.0 msec	0.1, 0.2, 0.5, and 1.0 msec	Same as Predicate Device
Stimulation Voltage	Voltage Mode: 0 to 10V	Voltage Mode: 0 to 10V	Same as Predicate Device
Multiple Lesions	Yes	Yes	Same as Predicate Device
Probe Connections	1 to 4	1 to 4	Same as Predicate Device
Accessory Compatibility	Compatible with Avanos-marketed RF Probes, Cannula/Introducers, Fluid Tubing Kits, and Split Grounding Pad.	Compatible with Avanos-marketed RF Probes, Cannula/Introducers, Fluid Tubing Kits, and Split Grounding Pad.	Same as Predicate Device (All COOLIEF* system components are used together to achieve the intended use. The subject CRG, QPU, and Therapy Cables are not compatible/interchangeable with the predicate PMG, PPU, or Therapy Cables.)
Type of Control	Automatic	Manual, Automatic, Pneumatic Foot Switch	Equivalent to Predicate Subject device no longer includes Manual or Foot Switch Controls, which were rarely used, optional features.
Overall Temperature Range	30°C - 95°C	30°C - 95°C	Same as Predicate Device

COOLIEF* Radiofrequency Generator (CRG)			
	Subject Device - CRG	**Predicate Device - PMG**	**Comment**
Lesioning Times	10 sec to 30 min	10 sec to 30 min	Same as Predicate Device
Pulse RF Time	10 to 900 seconds	10 to 900 seconds	Same as Predicate Device
Type of User Interface	Capacitive touch screen graphical user interface and rotary dial	Manual soft keys and rotary dial	Equivalent to Predicate Device Subject device includes touch screen display
System Safety Features	Automatic Shut-Off includes: • Out-of-range impedance and temperature • Over power, voltage, current Output of errors: • Fault indicator, fault code display and description Audible alarm	Automatic Shut-Off includes: • Out-of-range impedance and temperature • Over power, voltage, current Output of errors: • Fault indicator, fault code display and description Audible alarm	Same as Predicate Device
Contact Quality Monitoring	Yes	No	Subject Device circuitry and associated alarms were added to comply with IEC 60601-2-2.
Printer Output	No	No	Same as Predicate Device
WiFi Capability	No	No	Same as Predicate Device
Internet Connectivity	No	No	Same as Predicate Device
Sterility	Supplied non-sterile; Non-sterilizable	Supplied non-sterile; Non-sterilizable	Same as Predicate Device

COOLIEF* Quad Pump Unit (QPU)			
	Subject Device COOLIEF* Radiofrequency Generator System	**Predicate Peristaltic Pump**	**Comment**
Device Name (510(k))	COOLIEF* Quad Pump Unit, QPU (K192491)	Baylis Peristaltic Pump Unit, PPU (K072478)	
Pump Flow Rate	>18mL/min	>18mL/min	Same as Predicate Device
Pump Power Requirement	24VDC from RF Generator, 1000mA max	24VDC from RF Generator, 1000mA max	Same as Predicate Device
Sterility	Supplied non-sterile; Non-sterilizable	Supplied non-sterile; Non-sterilizable	Same as Predicate Device

COOLIEF* Therapy Cables			
	Subject Devices – MRF, MCRF, and TDP2	**Predicate Devices – MRF, MCRF, and TDP2 (K072478)**	**Comment**
Device Name (510(k))	Avanos Accessory Therapy Cables: • COOLIEF* Multi-RF Therapy Cable, MRF • COOLIEF* Multi-Cooled Therapy Cable, MCRF • COOLIEF* TransDiscal* Y-Connector Cable, TDP2	Baylis Accessory Therapy Cables: • COOLIEF* Multi-RF Therapy Cable, MRF • COOLIEF* Multi-Cooled Therapy Cable, MCRF • COOLIEF* TransDiscal* Y-Connector Cable, TDP2	
Cable Length	8 Ft	8 Ft	Same as Predicate Device
Probe Connections - Distal End	Pinned and keyed to be compatible with Avanos-marketed probes	Pinned and keyed to be compatible with Avanos-marketed probes	Same as Predicate Device
Number of Probe Connections	Two (TDP2) Four (MRF & MCRF)	Two (TDP2) Four (MRF & MCRF)	Same as Predicate Device
Key Cable Materials	Internal Materials: Copper/Nickel External Materials: Silicone & Thermoplastic elastomer	Internal Materials: Copper/Nickel External Materials: Silicone & Thermoplastic elastomer	Same as Predicate Device
Sterility	Supplied non-sterile; Non-sterilizable	Supplied non-sterile; Non-sterilizable	Same as Predicate Device

Summary of Non-Clinical Testing (Performance Testing)

Non-Clinical Performance Data

The following performance data were provided in support of the substantial equivalence determination for the subject COOLIEF* Radiofrequency Generator (CRG) System. Performance testing of the subject device was conducted to demonstrate that the modified device continued to meet performance specifications. Results of design verification and validation activities did not raise any new or different issues of safety or effectiveness. The risk management process was used throughout the non-clinical verification activities in accordance with ISO 14971. The following verification tests were conducted.

Bench Testing Performed	Result
COOLIEF* RF Generator Hardware Performance	Pass
Quad Pump Unit Flow-Rate Verification	Pass
Therapy Cable Mechanical Testing	Pass
Software Verification and Validation	Pass
Temperature Control - Benchtop and Perfused Tissue	Pass
Bench-Top Lesion Validation	Pass
Transportation and Handling (Packaging)	Pass
IEC 60601-1 (Medical Electrical Equipment – General Requirements for basic safety and essential performance 2012, Edition 3.1, Class 1.	Pass
IEC 60601-1-2: 2014 (Medical Electrical Equipment - General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.	Pass
IEC 60601-2-2: 2009 (Fifth Ed.) 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
IEC 62366-1:2015 (Part 1: Application of Usability Engineering to Medical Devices.)	Pass
IEC 62304:2006 A1:2015 (Medical device software – software life cycle processes)	Pass

Clinical Performance Data

Clinical data was not applicable to these subject devices.

Conclusion

The differences between the subject COOLIEF* Radiofrequency Generator (CRG) System and predicate device Baylis Pain Management Generator-TD (K072478)) do not raise any new or different questions of safety or effectiveness. The subject COOLIEF* Radiofrequency Generator System is substantially equivalent to the predicate devices with respect to the indications for use, technology, material composition, which are not patient contacting, and performance.