Baylis Medical Company Inc.
May Tsai
Team Leader, Regulatory Affairs
2775 Matheson Blvd. East
Mississauga, L4W 4P7 Canada

January 2, 2019

Re: K181864
Trade/Device Name: Polaris RF Ablation System
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD, GXI
Dated: November 30, 2018
Received: December 3, 2018

Dear May Tsai:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

John Marler -S

Digitally signed by John Marler -S
Date: 2019.01.02 16:14:58 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181864

Device Name
Polaris RF Ablation System

Indications for Use *(Describe)*
The Polaris RF Ablation System is intended for the creation of radiofrequency lesions in nervous tissue.

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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7. 510(k) Summary

7.1 Submitter Information

A. *Company Name*: Baylis Medical Company Inc.

B. *Company Address*: 2775 Matheson Blvd. East
Mississauga, Ontario L4W 4P7
Canada

C. *Company Phone*: (905) 602-4875

D. *Company Facsimile*: (905) 602-5671

E. *Contact Person*: May Tsai, Regulatory & Scientific Affairs Team Leader

F. *Summary Prepared on*: 11-Jul-2018

7.2 Device Identification

A. *Device Trade Name*:

- Polaris RF Ablation System

B. *Device Common Name*:

- Radiofrequency lesion generator
- Radiofrequency lesion probe

C. *Classification Name*:

- CFR 882.4400 – Radiofrequency lesion generator
- CFR 882.4725 – Radiofrequency lesion probe

D. *Product Code*:

- GXD, GXI

E. *Device Class*: Class II

7.3 Identification of Predicate Device

Table 7.1: Predicate Devices

Predicate Device	Manufacturer	510(k)
Baylis Pain Management Generator-TD	Halyard Health*	K072478
Baylis TransDiscal System		K062937
Baylis Pain Management Cooled Probe		K053082
Baylis Pain Management Probe and Connector Cable		K002389
BMC RF Cannula		K972846

*Note: Originally submitted by Baylis Medical Company Inc. as the manufacturer, but product line has since been acquired by Halyard Health.

7.4 Indications for Use

The Polaris RF Ablation System is intended for the creation of radiofrequency lesions in nervous tissue.

7.5 Device Description

The Polaris RF Ablation System includes the following components:

1. Polaris Radiofrequency Generator and Desk Stand
2. Polaris Pump, Pump Cable and Desk Stand
3. Polaris Standard Connector Hub / Polaris Cooled Connector Hub
4. Polaris Footswitch
5. Polaris Cooled RF Probe Kit:
    i. Polaris Cooled RF Ablation Probe
    ii. Polaris Tube Kit
    iii. Polaris Introducer
6. Polaris Single-Use RF Probe
7. Polaris Reusable RF Probe
8. Polaris RF Cannula

The Polaris RF Ablation System is intended for the creation of radiofrequency lesions in nervous tissue. The system is designed to deliver controlled RF energy from the Polaris RF Generator to target tissues via the Polaris RF Probes for standard RF procedures or Polaris Cooled RF Probes for cooled RF

procedures. RF energy is applied based on the configured RF generator settings to create the desired lesions in the target tissue. The generator also delivers low frequency stimulation pulses during procedures.

During standard RF procedures, the Polaris RF Probe is used with a compatible Polaris RF Cannula to enable RF energy delivery via the active electrode to the target tissues. During cooled RF procedures with Polaris Cooled RF Probes, the system integrates a cooling mechanism by internally circulating water through the probes using the Polaris Pump Unit. This cooling results in minimal charring of the surrounding tissue and also prevents tissue from adhering to the electrodes. This allows for larger and more consistent ablation volumes to be achieved.

7.6 Comparison to Predicate Device

The intended use of the subject Polaris RF Ablation System is the same as the predicate devices. The indication for use of the Polaris RF Ablation System is the same, or a subset of, the indications for use of the predicate devices. The subject and predicate devices share the same fundamental scientific technology, including principles of operation and mechanism of action (**Tables 7.2 and 7.3**). Differences in design and technological characteristics between the proposed and predicate devices do not raise any new types of safety and effectiveness questions. Verification and validation test results provide reasonable assurance of the substantial equivalence of the Polaris RF Ablation System compared to the predicate system.

Table 7.2: Comparison of Subject and Predicate Devices – Overall System

	PREDICATE DEVICES					SUBJECT DEVICE	Identical / Substantially Equivalent (SE)
Device Name	Baylis Pain Management Generator-TD	TransDiscal (TD) System	BMC RF Cannula	BMC PM Probe and Connector Cable	Baylis PM Cooled Probe	Polaris RF Ablation System	N/A
510(k) #	K072478	K062937	K972846	K002389	K053082	K181864	N/A
Manufacturer	Halyard Health*					Baylis Medical Company Inc.	N/A
Class	II	II	II	II	II	II	YES/YES
Product Code, Regulation	GEI, 882.4400 GXD, 882.4400	GXI, 882.4725	GXI, 882.4725	GXI, 882.4725	GXI, 882.4725	GXD, 882.4400 GXI, 882.4725	YES/YES
Indications for Use	Baylis Pain Management Generator - TD; Model PMG-115-TD (For Domestic Use) and Model PMG-230-TD (For International Use) 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	The Baylis TD system, used in combination with the Baylis PM Generator, is indicated for the creation of RF heat lesions in nervous tissue including that which is situated in the intervertebral disc material.	The BMC RF Cannula is intended for use in RF heat lesion procedures for relief of pain	To create RF lesions in nervous tissue.	The Baylis PM Cooled Probe will be used in conjunction with a RF Generator to create RF lesions in nervous tissue.	The Polaris RF Ablation System is intended for the creation of RF lesions in nervous tissue.	NO/YES

	PREDICATE DEVICES					SUBJECT DEVICE	Identical / Substantially Equivalent (SE)
	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.						
Relevant System Components	RF Generator	Peristaltic Pump, Connector Cable Tube Kit Introducer Y-Connecting Cable	RF Cannula	Standard RF Probes (non-cooled)	Cooled RF Probe	RF Generator and Desk Stand Peristaltic Pump and Desk Stand, Pump Connector Cable Connector Hub RF Cannula Standard RF Probes (non-cooled) Cooled RF Probe kit (Cooled RF Probe, Tube Kit, Introducer)	NO/YES

	PREDICATE DEVICES	SUBJECT DEVICE	Identical / Substantially Equivalent (SE)
User	Physicians familiar with RF lesion techniques	Physicians familiar with RF lesion techniques	YES/YES
Anatomical Site of Use	Nervous tissue	Nervous tissue	YES/YES
Access Method	Percutaneous	Percutaneous	YES/YES
Energy Type	Radiofrequency	Radiofrequency	YES/YES
Principle of Operation	Operator controlled; RF delivered from RF generator to compatible RF probes	Operator controlled; RF delivered from RF generator to compatible RF probes	YES/YES
Mechanism of Action	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	YES/YES
System Feedback Mechanism	Temperature controlled	Temperature controlled	YES/YES
Ability to Make Multiple Lesions	Yes	Yes	YES/YES

Table 7.3: Comparison of Subject and Predicate Devices – Relevant Components

	PREDICATE DEVICE	SUBJECT DEVICE	Identical/ SE
RF GENERATOR			
Device Name	Baylis Pain Management Generator-TD	Polaris Radiofrequency Generator	N/A
510(k) #	K072478	K181864	N/A
Available Generator Modes	Standard RF Mode • Stimulation (Sensory/Motor) • Pulsed RF (Single RF, Multi-RF, Bipolar RF) • RF lesion (Single RF, Multi-RF, Bipolar RF) Cooled RF Mode • Stimulation (Sensory/Motor) • RF lesion (Single RF, Multi-RF, Bipolar RF)	Standard RF Mode • Stimulation (Sensory/Motor) • Pulsed RF (Single RF, Multi-RF, Bipolar RF) • RF lesion (Single RF, Multi-RF, Bipolar RF) Cooled RF Mode • Stimulation (Sensory/Motor) • RF lesion (Single RF, Multi-RF, Bipolar RF)	YES/YES
Maximum Power Output	50 Watts	50 Watts	YES/YES
Operating Frequency Waveform	461 kHz Sinusoidal	465 kHz Sinusoidal	NO/YES
Temperature Monitoring Thermocouple (RF modes)	Yes	Yes	YES/YES
Display Parameters	Real time temperature, impedance, power and voltage (pulsed RF mode)	Real time temperature, impedance, power and voltage (pulsed RF mode)	YES/YES
Safety Features	• Automatic shut-off for: ○ Out-of-range impedance and temperature ○ Over power, voltage, current • Output of errors, including: ○ Fault indicator, fault code display and description ○ Audible alarm	• Automatic shut-off for: ○ Out-of-range impedance and temperature ○ Over power, voltage, current • Output of errors, including: ○ Alert icon, fault code display and description ○ Audible alarm	YES/YES
Touchscreen	No	Yes	NO/YES
Used with Desk Stand	No	Yes	NO/YES
Used with Optional Footswitch	Yes	Yes	YES/YES
Environment	Supplied non-sterile; Non-sterilisable	Supplied non-sterile; Non-sterilisable	YES/YES

		PREDICATE DEVICE	SUBJECT DEVICE	Identical/ SE
COOLED RF PROBE				
Device Name		PM Cooled Probe	Polaris Cooled RF Ablation Probe	N/A
510(k) #		K053082	K181864	N/A
Probe Configuration		Monopolar	Monopolar	YES/YES
Includes Thermocouple for Tissue Temperature Measurement		Yes	Yes	YES/YES
Location of Thermocouple		Exposed at probe distal tip	Embedded within probe distal tip	NO/YES
Patient-Contact Materials	**Shaft, Thermocouple**	Stainless steel	Stainless steel	YES/YES
	Insulation	Polyimide	Polyimide	
Key Non-patient Contact Materials	**Handle**	Acetal	ABS	NO/YES
	Cable	Silicone	Silicone	
	Tubing	Polyvinyl chloride	Polyvinyl chloride	
	Luer lock	Polycarbonate	Polycarbonate	
Key Dimensions	**Shaft Diameter**	18 Gauge	18 Gauge	NO/YES
	Active Tip Lengths	2, 4, 5.5, 6 mm	4, 5.5 mm	
	Compatible Introducer Lengths	50, 75, 100, 150 mm	50, 100, 150 mm	
	Cable	48” (length); 3.80 mm (OD)	48” (length); 3.80 mm (OD)	
	Tubing	48” (length); 3.18 mm (OD)	48” (length); 3.18 mm (OD)	
Environment		Provided sterile; Single use	Provided sterile; Single use	YES/YES
Sterilization Method; Sterility Assurance Level (SAL)		Ethylene oxide; 10^{-6}	Ethylene oxide; 10^{-6}	YES/YES
TUBE KIT				
Device Name		TransDiscal Tube Kit	Polaris Tube Kit	N/A
510(k) #		K062937	K181864	N/A
Key non-patient Contact Materials	**Tubing**	Tygon	Tygon	NO/YES
	Burette, Female Luer Cap, Luer Locks	Polycarbonate	Polycarbonate	
	Crimp	N/A	Stainless steel	
Key Dimensions	**Tubing Length**	140”	140”	YES/YES
	Burette Capacity	70 mL	70 mL	
Environment		Provided sterile; Single use	Provided sterile; Single use	YES/YES
Sterilization Method; Sterility Assurance Level (SAL)		Ethylene oxide; 10^{-6}	Ethylene oxide; 10^{-6}	YES/YES

		PREDICATE DEVICE	SUBJECT DEVICE	Identical/ SE
INTRODUCER				
Device Name		TransDiscal Introducer	Polaris Introducer	N/A
510(k) #		K062937	K181864	N/A
Comprises Cannula and Stylet		Yes	Yes	YES/YES
Depth Markers		Yes	Yes	YES/YES
Patient-contact Materials	**Shaft Introducer, Stylet**	Stainless steel	Stainless steel	NO/YES
	Insulation	Polyimide	Polyimide	
	Hub	Unknown	Copolyester	
Key Dimensions	**Shaft Outer Diameter**	17 Gauge	17 Gauge	NO/YES
	Usable Length(s)	50, 75, 100, 150 mm	50, 100, 150mm	
Environment		Provided sterile; Single use	Provided sterile; Single use	YES/YES
Sterilization Method; Sterility Assurance Level (SAL)		Ethylene oxide; 10^{-6}	Ethylene oxide; 10^{-6}	YES/YES
SINGLE-USE RF PROBE				
Device Name		Pain Management Probe	Polaris Single-Use RF Probe	N/A
510(k) #		K002389	K181864	N/A
Configuration		Monopolar	Monopolar	YES/YES
Used with Compatible Cannula		Yes	Yes	YES/YES
Thermocouple for Tissue Temperature Measurement		Yes	Yes	YES/YES
Patient-contact Materials	**Shaft, Stylet**	Stainless steel	Stainless steel	YES/YES
Key Dimensions	**Shaft Diameter**	24, 28, 31 Ga	28 Ga	NO/YES
	Compatible Cannula Length(s)	50, 54, 60, 100, 145, 200 mm	50, 100, and 150 mm	
Environment		Provided non-sterile; Re-sterilisable (steam)	Provided sterile; Single use	NO/YES
Sterilization Method; Sterility Assurance Level (SAL)		N/A	Ethylene oxide; 10^{-6}	NO/YES
REUSABLE RF PROBE				
Device Name		Pain Management Probe	Polaris Reusable RF Probe	N/A
510(k) #		K002389	K181864	N/A
Configuration		Monopolar	Monopolar	YES/YES
Used with Cannula		Yes	Yes	YES/YES
Thermocouple for Tissue Temperature Measurement		Yes	Yes	YES/YES

		PREDICATE DEVICE	SUBJECT DEVICE	Identical/ SE
Patient-contact Materials	**Shaft, Stylet**	Stainless steel or nitinol	Stainless steel or nitinol	YES/YES
Key Dimensions	**Shaft Diameter**	24, 28, 31 Ga	28 Ga	NO/YES
	Compatible Cannula Length(s)	50, 54, 60, 100, 145, 200 mm	50, 100, and 150 mm	
Environment		Provided non-sterile; Re-sterilisable (steam)	Provided non-sterile; Re-sterilisable (steam)	YES/YES
RF CANNULA				
Device Name		BMC RF Cannula	Polaris RF Cannula	N/A
510(k) #		K972846	K181864	N/A
Patient-contact Materials	**Shaft, Stylet**	Stainless steel	Stainless steel	YES/YES
	Shaft Insulation	Polyethylene terephthalate	Polyethylene terephthalate	
	Hub	Copolyester	Copolyester	
Key Dimensions	**Shaft Diameter**	16, 18, 20, 21, 22 Ga	16, 18, 20, 22 Ga	NO/YES
	Usable Length	50, 54, 60, 100, 145, 200 mm	50, 100, 150 mm	
	Bare Active Tip	2, 4, 5, 10, 15 mm	5, 10 mm	
Tip Configurations		Straight sharp Straight blunt Curved sharp Curved blunt	Straight sharp Curved sharp Curved blunt	NO/YES
Environment		Provided sterile; Single use	Provided sterile; Single use	YES/YES
Sterilization Method; Sterility Assurance Level (SAL)		Ethylene oxide; 10^{-6}	Ethylene oxide; 10^{-6}	YES/YES
PUMP UNIT				
Device Name		TransDiscal Pump Unit	Polaris Pump Unit	N/A
510(k) #		K062937	K181864	N/A
Number of Pump Heads		Two	Two	YES/YES
Pump Controlled by Generator		Yes	Yes	YES/YES
Used with Tube Kit(s)		Yes	Yes	YES/YES
Safety Switch		Yes	Yes	YES/YES
Used with Desk Stand		No	Yes	NO/YES
Environment		Supplied non-sterile; Non-sterilisable	Supplied non-sterile; Non-sterilisable	YES/YES
CONNECTOR HUB				
Device Name		TransDiscal Y-Connecting Cable	Polaris Connector Hub	N/A
510(k) #		K062937	K181864	N/A
Number of Probe Connections Possible		Two	Four	NO/YES

		PREDICATE DEVICE	SUBJECT DEVICE	Identical/ SE
Connector	**Probe**	5-pin female	7-pin female	NO/YES
	Generator	19-pin male	33-pin HG4 male	
Key Cable Materials		Silicone, Thermoplastic elastomer	Thermoplastic elastomer, injection molded plastic	NO/YES
Cable Length		9 feet	8 feet	NO/YES
Environment		Supplied non-sterile; Non-sterilisable	Supplied non-sterile; Non-sterilisable	YES/YES

7.7 Performance Testing

Performance testing was completed to demonstrate substantial equivalence of the Polaris RF Ablation System and relevant system components to the identified predicate devices in **Table 7.1**. The system components were subjected to the verification and validation testing listed in **Table 7.4**.

Table 7.4: Performance Testing of Subject Device

Tests	Test Method Summary	Results
Polaris Re-Usable RF Probe		
Mechanical	The following tests were conducted to verify whether the subject device was capable of withstanding the relevant mechanical stresses without failure: • Temperature Test • Pull Test • Cleaning and Sterilization Reuse Test • Mechanical Reuse Test • Mechanical Test (Flexion) • Continuity Test • Functional Test	All samples passed the acceptance criteria. Results confirmed compliance of the device with IEC 60601-2-2:2009 and support substantial equivalence with the predicate device.
Electrical	Electrical verification was conducted through comparison with the Polaris Standard Single-Use Probe to verify whether the device was capable of withstanding the relevant electrical stresses without failure.	The device was verified to meet the requirements of IEC 60601-1:2005+A1:2012 and IEC 60601-2-2:2009. Results support substantial equivalence with the predicate device.

Tests	Test Method Summary	Results
Biocompatibility	Biocompatibility of the subject device was demonstrated through comparisons to similar legally marketed devices as per current ISO 10993-1 requirements and the FDA guidance, *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*.	Results confirmed compliance of the device with the current ISO 10993-1 requirements and support substantial equivalence with the predicate device.
Packaging	Ship testing was performed to ensure the integrity of the subject device packaging through the rigors of shipping and handling.	All packaging met relevant requirements. Results support substantial equivalence with the predicate device.
Cleaning and Sterilization	The recommended reprocessing methods provided in the Instructions for use were validated to ensure the recommended parameters and method could achieve a Sterility Assurance Level of 10^{-6}.	The device was verified to meet the requirements of AAMI TIR12, AAMI TIR30 and ANSI/AAMI ST81 requirements and the FDA guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*. Results support substantial equivalence with the predicate device.
Polaris Single-Use RF Probe		
Mechanical	The following tests were conducted to verify whether the subject device was capable of withstanding the relevant mechanical stresses without failure: • Temperature Test • Pull Test • Durability Test • Mechanical Test (Flexion) • Continuity Test • Functional Test	All samples passed the acceptance criteria. Results confirmed compliance of the device with IEC 60601-2-2:2009 and support substantial equivalence with the predicate device.

Tests	Test Method Summary	Results
Electrical	The following tests were conducted to verify whether the subject device was capable of withstanding the relevant electrical stresses without failure: • High Frequency Leakage Current Test – Cable • High Frequency Dielectric Strength Test – Cable • High Frequency Dielectric Strength Test – Handle • Mains Frequency Dielectric Strength Test – Cable • Mains Frequency Dielectric Strength Test – Handle • Mains Frequency Dielectric Strength Test – Connector	All samples passed the acceptance criteria. Results confirmed compliance of the device with IEC 60601-1:2005+A1:2012 and IEC 60601-2-2:2009 and support substantial equivalence with the predicate device.
Biocompatibility	Biocompatibility of the subject device was demonstrated through comparisons to similar legally marketed devices as per current ISO 10993-1 requirements and the FDA guidance, *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*.	Results confirmed compliance of the device with the current ISO 10993-1 requirements and support substantial equivalence with the predicate device.
Packaging	Ship testing was performed to ensure the integrity of the subject device packaging through the rigors of shipping and handling. The seal strength and sterile barrier integrity was validated per ANSI/AAMI/ISO 11607-1 and 11607-2 over the shelf life of the device.	The device packaging met relevant requirements. Results confirmed compliance of device packaging with ANSI/AAMI/ISO 11607-1 and 11607-2 and support substantial equivalence with the predicate device.

Tests	Test Method Summary	Results
Polaris RF Cannula		
Mechanical	The following tests were conducted to verify whether the subject device was capable of withstanding the relevant mechanical stresses without failure: • Positive Pressure Liquid Leakage Test • Sub-atmospheric Pressure Air Leakage Test • Resistance to Separation Test • Stress Cracking Test • Hub Strength Test	All samples passed the acceptance criteria. Results confirmed the device met with the mechanical requirements of ISO 80369-7:2016, ISO 594-1:1986 and ISO 7864:2016 and support substantial equivalence with the predicate device.
Electrical	The following tests were conducted to verify whether the subject device was capable of withstanding the relevant electrical stresses without failure: • High Frequency Leakage Current Test • High Frequency Dielectric Strength Test • Mains Frequency Dielectric Strength Test	All samples passed the acceptance criteria. Results confirmed compliance of the device with IEC 60601-1:2005+A1:2012 and IEC 60601-2-2:2009 and support substantial equivalence with the predicate device.
Biocompatibility	Biocompatibility of the subject device was demonstrated through biological testing as per current ISO 10993-1 requirements and the FDA guidance, *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".*	Results confirmed compliance of the device with the current ISO 10993-1 requirements and support substantial equivalence with the predicate device.
Packaging	Ship testing was performed to ensure the integrity of the subject device packaging through the rigors of shipping and handling. The seal strength and sterile barrier integrity was validated per ANSI/AAMI/ISO 11607-1 and 11607-2 over the shelf life of the device.	The device packaging met relevant requirements. Results confirmed compliance of device packaging with ANSI/AAMI/ISO 11607-1 and 11607-2 and support substantial equivalence with the predicate device.

Tests	Test Method Summary	Results
Polaris Cooled RF Probe Kit		
Mechanical	The following tests were conducted to verify whether the Polaris Cooled RF Probe was capable of withstanding the relevant mechanical stresses without failure: • Leak/Pressure Test • Pull Test • Temperature Test • Tip Compression Test • Mechanical Test (Flexion) • Continuity Test • Functional Test	All samples passed the acceptance criteria. Results confirmed compliance of the device with IEC 60601-2-2:2009 and support substantial equivalence with the predicate device.
Mechanical	The following tests were conducted to verify whether the Polaris Introducer was capable of withstanding the relevant mechanical stresses without failure: • Resistance to Separation from Unscrewing Test • Resistance to Separation Test	All samples passed the acceptance criteria. Results support substantial equivalence with the predicate device.
Electrical	The following tests were conducted to verify whether the Polaris Cooled RF Probe was capable of withstanding the relevant electrical stresses without failure: • High Frequency Leakage Current Test – Cable • High Frequency Leakage Current Test – Shaft • High Frequency Dielectric Strength Test – Cable • High Frequency Dielectric Strength Test – Handle/Shaft • Mains Frequency Dielectric Strength Test – Cable • Mains Frequency Dielectric Strength Test – Handle/Shaft • Mains Frequency Dielectric Strength Test Connector	All samples passed the acceptance criteria. Results confirmed compliance of the device with IEC 60601-1:2005+A1:2012 and IEC 60601-2-2:2009 and support substantial equivalence with the predicate device.

Tests	Test Method Summary	Results
Biocompatibility	Biocompatibility of the Polaris Cooled RF Probe and Polaris Introducer was demonstrated through biological testing and comparisons to similar legally marketed devices as per current ISO 10993-1 requirements and the FDA guidance, *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".*	Results confirmed compliance of the devices with the current ISO 10993-1 requirements and support substantial equivalence with the predicate devices.
Packaging	Ship testing was performed to ensure the integrity of the subject device packaging through the rigors of shipping and handling. The seal strength and sterile barrier integrity was validated per ANSI/AAMI/ISO 11607-1 and 11607-2 over the shelf life of the device.	The subject device packaging met relevant requirements. Results confirmed compliance of device packaging with ANSI/AAMI/ISO 11607-1 and 11607-2 and support substantial equivalence with the predicate device.
Polaris Radiofrequency Generator		
Verification	Testing was conducted to verify the function of the subject device, including electrical testing of the following hardware components: • RF board • User Interface Board • Multiplexer board	The subject device met all relevant requirements. Results support substantial equivalence with the predicate device.
Packaging	Ship testing was performed to ensure the integrity of the subject device packaging through the rigors of shipping and handling.	All packaging met relevant requirements. Results support substantial equivalence with the predicate device.

Tests	Test Method Summary	Results
Polaris Pump Unit		
Verification	Testing was conducted to verify specified design requirements of the subject device, including hardware. Performance was assessed in test cases covering the following aspects: • Inspection • Configuration and Installation • Operation • Environment and Service Life	The subject device met all relevant requirements. Results support substantial equivalence with the predicate device.
Packaging	Ship testing was performed to ensure the integrity of the subject device packaging through the rigors of shipping and handling.	All packaging met relevant requirements. Results support substantial equivalence with the predicate device.
Polaris Connector Hub		
Verification	Testing was conducted to verify specified design requirements of the subject device, including hardware. Performance was assessed through various test cases, including: • Cable Pull Test • Cable Impulse Test • Device Identification	The subject device met all relevant requirements. Results confirmed compliance of the device with Baylis self-enforced requirements and support substantial equivalence with the predicate device.
Packaging	Ship testing was performed to ensure the integrity of the device packaging through the rigors of shipping and handling.	All packaging met relevant requirements. Results confirmed compliance of device packaging with Baylis self-enforced requirements and support substantial equivalence with the predicate device.
Polaris Footswitch		
Packaging	Ship testing was performed to ensure the integrity of the subject device packaging through the rigors of shipping and handling.	All packaging met relevant requirements. Results support substantial equivalence with the predicate device.

Tests	Test Method Summary	Results
Polaris RF Ablation System		
Electrical Product Safety	The Polaris RF Generator, together with relevant accessories and detachable parts, was tested to demonstrate compliance with the applicable requirements of IEC 60601-1:2005+A1:2012 (including national deviations as per ANSI AAMI ES 60601-1:2005(R) 2012 + A1:2012) and IEC 60601-2-2: 2009.	The subject device met all relevant requirements. Results confirmed compliance of the device with IEC 60601-1:2005+A1:2012 and IEC 60601-2-2:2009 and support substantial equivalence with the predicate device.
Electromagnetic Compatibility	The Polaris RF Generator, together with applicable system components, was tested to demonstrate compliance with the applicable requirements of IEC 60601-1-2:2014.	The subject device met all relevant requirements. Results confirmed compliance of the device with IEC 60601-1-2:2014 and support substantial equivalence with the predicate device.
Benchtop Lesion Validation	Comparative lesion validation testing was performed using a soft tissue model to demonstrate the substantially equivalent ablation performance of the subject and predicate systems. Testing was performed for both single and multi-probe scenarios.	The subject device met all relevant requirements. Results support substantial equivalence with the predicate device.
Usability	Testing was performed to verify and validate the usability requirements of the subject Polaris RF Ablation System. Elements captured included normal use cases, a foreseeable worst-case use scenario, and testable requirements for primary operating functions.	The device met all relevant requirements. Results support substantial equivalence with the predicate device.

Tests	Test Method Summary	Results
Software	Software verification and validation was completed for the subject device. FDA's current *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* was used to determine the Level of Concern for the software in the subject Polaris RF Ablation System.	The device met all relevant requirements. Results support substantial equivalence with the predicate device.

All test requirements were met as specified by applicable standards and the test protocols. Results demonstrate that the Polaris RF Ablation System functions as intended and is as safe and effective as the predicate device.

7.8 Conclusions

The intended use of the subject Polaris RF Ablation System is the same as the predicate devices. The indications for use of the Polaris RF Ablation System is the same, or a subset of, the indications for use of the predicate devices. The fundamental scientific technology of the Polaris RF Ablation System, including principles of operation and mechanism of action, is the same as the predicate devices. Differences in design and technological characteristics between the subject and predicate devices do not raise any new types of questions of safety and effectiveness. Verification and validation test results support the substantial equivalence of the Polaris RF Ablation System to the predicate system.