July 19, 2024

Varian Medical Systems, Inc.
Lynn Allman
Sr. Director Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

Re: K240480
Trade/Device Name: IntelliBlate Microwave Ablation System Console (IB-CON); IntelliBlate Microwave Ablation System Mobile Cart (IB-CART); IntelliBlate Ximitry Probe Assembly, 13G x 15cm (IB-XPA-1315); IntelliBlate Ximitry Probe Assembly, 13G x 20cm (IB-XPA-1320); IntelliBlate Ximitry Probe Assembly, 13G x 27cm (IB-XPA-1327)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: June 17, 2024
Received: June 18, 2024

Dear Lynn Allman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2024.07.19 13:35:14 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240480

Device Name
IntelliBlate Microwave Ablation System Console (IB-CON); IntelliBlate Microwave Ablation System Mobile Cart (IB-CART); IntelliBlate Ximitry Probe Assembly, 13G x 15cm (IB-XPA-1315); IntelliBlate Ximitry Probe Assembly, 13G x 20cm (IB-XPA-1320); IntelliBlate Ximitry Probe Assembly, 13G x 27cm (IB-XPA-1327).

Indications for Use *(Describe)*
IntelliBlate Microwave Ablation System:

The IntelliBlate Microwave Ablation System is intended for coagulation (ablation) of soft tissue.
The IntelliBlate Microwave Ablation System is not intended for use in cardiac procedures.

IntelliBlate Ximitry Probe Assembly:
The IntelliBlate Ximitry Probe Assembly, used with the IntelliBlate Microwave Ablation System is intended for coagulation (ablation) of soft tissue.
The IntelliBlate Ximitry Probe Assembly is not intended for use in cardiac procedures.

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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Varian Medical Systems, Inc
3100 Hansen Way
Palo Alto, CA 94304-1038

Telephone: 1.650.493.4000
Toll Free: 800.544.4636
www.varian.com

PREMARKET NOTIFICATION

K240480 510(k) Summary
IntelliBlate Microwave Ablation System and Accessories
The following information is provided as required by 21 CFR 807.92

I. Submitter's Information:

Name and Address:	Varian Medical Systems Inc.
	9825 Spectrum Drive, Building 2 Austin, TX 78717
Contact Name:	Lynn Allman, Senior Director Regulatory Affairs
E-mail:	submissions.support@varian.com
Date Prepared:	July 17, 2024

II. Device Information:

Proprietary Name:	IntelliBlate Microwave Ablation System and Accessories
Common/ Usual Name:	System, Ablation, Microwave and Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4400
Product Code	NEY

III. Predicate Devices:

Emprint Ablation System with Thermosphere Technology (K200796)
Neuwave Certus 140 2.45 GHz Ablation System and Accessories (K100744)

IV. Subject Device Description:

The IntelliBlate Microwave Ablation System is a software-controlled microwave therapy delivery system with graphical user interface and hardware to control and monitor the therapy delivered to the target tissues.

The system consists of a 2.45 GHz microwave generator (console) with an integrated peristaltic pump assembly for coolant fluid delivery, a coolant Fluid Mount and an optional mobile cart for the console. Accessories for the system include IntelliBlate Ximitry Probe Assembly – a sterile, single-use disposable microwave ablation assembly with ablation probes and a cassette for coolant fluid tubing (closed cooling circuit).

V. Intended Use/ Indications of Use Statement:

IntelliBlate Microwave Ablation System

The IntelliBlate Microwave Ablation System is intended for coagulation (ablation) of soft tissue.

The IntelliBlate Microwave Ablation System is not intended for use in cardiac procedures.

IntelliBlate Ximitry Probe Assembly

The IntelliBlate Ximitry Probe Assembly, used with the IntelliBlate Microwave Ablation System is intended for coagulation (ablation) of soft tissue.

The IntelliBlate Ximitry Probe Assembly is not intended for use in cardiac procedures.

VI. Substantial Equivalence Discussion:

The following table compares the subject device to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence.

Table 1: Comparison of Technological Characteristics between subject and predicate devices

Features/ Characteristics	**Subject Device** IntelliBlate Microwave Ablation System and Accessories	**Predicate Device** Emprint Ablation System with Thermosphere Technology (K200796)	**Predicate Device** Neuwave Certus 140 2.45 GHz Ablation System and Accessories (K100744)	**Comparison**
Product code, FDA regulation and device class	NEY, 21 CFR 878.4400 and Class II	NEY, 21 CFR 878.4400 and Class II	NEY, 21 CFR 878.4400 and Class II	Same
510(k) clearance(s)	No prior 510(k) clearances	K200796	K100744	Subject device is a new device with no prior regulatory clearances.
Manufacturer	Varian Medical Systems	Covidien	Neuwave Medical Inc.	Different manufacturer
Prescription (Rx only)	Yes	Yes	Yes	Same
Intended Use	Intended for coagulation (ablation) of soft tissue in laparoscopic, intraoperative, and percutaneous ablation procedures	Intended for coagulation (ablation) of soft tissue in laparoscopic, intraoperative, and percutaneous ablation procedures.	The Neuwave Medical Certus 140 2.45 GHz Ablation System and Accessories are intended for the ablation (coagulation) of soft tissue. The Certus 140™ 2.45 GHz Ablation System is not intended for use in cardiac procedures. NeuWave recommends against the use of the Certus 140 2.45 GHz Ablation System in the following situations: * Pregnant patients - potential risks to patient and/or fetus have not been established * Patients with implantable pacemakers or other electronic implants. Implanted electronic devices may be adversely affected by microwave power The system is designed for facility use and should only be used under the orders of a clinician.	Same indication of use –subject and predicate devices are indicated for coagulation (ablation) of soft tissue. Subject device does not include percutaneous, laparoscopic, endoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors.

Features/ Characteristics	**Subject Device** IntelliBlate Microwave Ablation System and Accessories	**Predicate Device** Emprint Ablation System with Thermosphere Technology (K200796)	**Predicate Device** Neuwave Certus 140 2.45 GHz Ablation System and Accessories (K100744)	**Comparison**
Indications for Use Statement for IntelliBlate Microwave Ablation System	The IntelliBlate Microwave Ablation System is intended for coagulation (ablation) of soft tissue. The IntelliBlate Microwave Ablation System is not intended for use in cardiac procedures.	The Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, endoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors. The Emprint™ Ablation System is not intended for use in cardiac procedures.	The Neuwave Medical Certus 140 2.45 GHz Ablation System and Accessories are intended for the ablation (coagulation) of soft tissue. The Certus 140™ 2.45 GHz Ablation System is not intended for use in cardiac procedures. NeuWave recommends against the use of the Certus 140 2.45 GHz Ablation System in the following situations: * Pregnant patients - potential risks to patient and/or fetus have not been established * Patients with implantable pacemakers or other electronic implants. Implanted electronic devices may be adversely affected by microwave power The system is designed for facility use and should only be used under the orders of a clinician.	Same indication of use –subject and predicate devices are indicated for coagulation (ablation) of soft tissue. Subject device does not include percutaneous, laparoscopic, endoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors.
Indications for Use Statement for IntelliBlate Ximitry Probe Assembly	The IntelliBlate Ximitry Probe Assembly, used with the IntelliBlate Microwave Ablation System is intended for coagulation (ablation) of soft tissue. The IntelliBlate Ximitry Probe Assembly is not intended for use in cardiac procedures.	The Covidien Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, endoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors. The Covidien Emprint™ Ablation System is not intended for use in cardiac procedures.	The Neuwave Medical Certus 140 2.45 GHz Ablation System and Accessories are intended for the ablation (coagulation) of soft tissue. The Certus 140™ 2.45 GHz Ablation System is not intended for use in cardiac procedures. NeuWave recommends against the use of the Certus 140 2.45 GHz Ablation System in the following situations:	Same indication of use –subject and predicate devices are indicated for coagulation (ablation) of soft tissue. Subject device does not include percutaneous, laparoscopic, endoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors.

Features/ Characteristics	Subject Device IntelliBlate Microwave Ablation System and Accessories	Predicate Device Emprint Ablation System with Thermosphere Technology (K200796)	Predicate Device Neuwave Certus 140 2.45 GHz Ablation System and Accessories (K100744)	Comparison
			* Pregnant patients - potential risks to patient and/or fetus have not been established * Patients with implantable pacemakers or other electronic implants. Implanted electronic devices may be adversely affected by microwave power The system is designed for facility use and should only be used under the orders of a clinician.	
Operating Principle for microwave ablation	Microwave ablation is heating of the target tissue based on agitation of water molecules inducing cellular death via coagulation (ablation) necrosis	Microwave ablation is heating of the target tissue based on agitation of water molecules inducing cellular death via coagulation (ablation) necrosis	Microwave ablation is heating of the target tissue based on agitation of water molecules inducing cellular death via coagulation (ablation) necrosis	Same
System Configuration				
Generator	Tabletop Generator (console)	Cart mounted Generator	Cart mounted Generator	Same
No of independent ablation channels	2	1	3	Subject device supports 2 independent ablation channels
Cooling System	Peristaltic Pump Assembly integrated into the generator for each ablation channel	Peristaltic Pump Assembly separate and external to the generator	CO2 based cooling system	Subject and predicate device (K200796) has peristaltic pump assembly for cooling of the ablation probes.
Touch Screen/ Graphical User Interface	Yes	No (Physical Buttons and digital display)	Yes	GUI/ Touch Screen
Accessories				
Ablation Probe Assembly	Includes ablation probe, coolant tubing, coolant spike, integrated cassette for coolant delivery and power cable.	Includes ablation probe, coolant tubing, coolant spike and power cable. Coolant delivery is external via manual connection to the external pump.	Includes a probe handle, a 1.4M cable, CO2 gas coolant tubing and a connector assembly. An intermediate junction box or Power Distribution	Subject device does not need an additional reusable cable to connect probe to the generator.

Features/ Characteristics	Subject Device IntelliBlate Microwave Ablation System and Accessories	Predicate Device Emprint Ablation System with Thermosphere Technology (K200796)	Predicate Device Neuwave Certus 140 2.45 GHz Ablation System and Accessories (K100744)	Comparison
	Optional accessories – laser alignment disc and depth guides for ablation probes		Module (PDM) is used between the probe and console.	
Optional Accessories	Temperature sensor probe, mobile cart	Remote Temperature Probe, mobile cart, footswitch	Footswitch	Similar optional accessories
Ablation				
Ablation features	Ablation, Track Ablation and Needle Lock	Ablation. Device can be used for track ablation as a use workflow.	Ablation, Cauterize (track ablation), Tissue Loc, Planar Coagulation	Additional pre-configured ablation features in subject device
Target Ablation time	Up to 10 minutes.	Up to 10 minutes	Up to 10 minutes	Same
Generator				
Device Usage	Multi-use	Multi-use	Multi-use	Same
Compatible Disposable/ Single Use Devices	Microwave ablation probe (up to 2) Optional Temperature Sensor Probe (up to 2)	Microwave ablation probe (1) Optional Remote Temperature Probe (1)	Microwave ablation probe (up to 3)	Subject device can connect up to 2 probes
Generator Output Frequency	2.45GHz ± 50MHz	2.45GHz ± 50MHz	2.45GHz ± 25MHz	Same
Maximum RF power for ablation (measured at output port):	170W (single needle ablation) 2x 150W (double needle ablation)	150W (single needle ablation)	140W (single needle ablation) 2x 95W (double needle ablation) 3x 65W (triple needle ablation)	Increased output power to compensate for cable losses.
Power Settings	Adjusts microwave power setpoint in 5-watt increments	Adjusts microwave power setpoint in 5-watt increments.	Adjusts microwave power setpoint in 5-watt increments	Same
Temperature Monitoring	Yes	Yes	Yes	Same
Safety Feature - Automatic system Shutdown when ablation probe temperature	Yes	Yes	Yes	Same

Features/ Characteristics	Subject Device IntelliBlate Microwave Ablation System and Accessories	Predicate Device Emprint Ablation System with Thermosphere Technology (K200796)	Predicate Device Neuwave Certus 140 2.45 GHz Ablation System and Accessories (K100744)	Comparison
exceed limits and due to high reflected power				
Safety Standard Compliance	IEC 60601-1, 60601-1-6, 60601-2-6, 60601-1-2	IEC 60601-1, 60601-1-6, 60601-2-6, 60601-1-2	IEC 60601-1, 60601-2-2, 60601-2-6, 60601-1-2	Same
Potential Equalization	Equalization terminal	Equalization terminal	Equalization terminal	Same
Electronic Interfaces for Interoperability	USB	USB	USB	Same
Operating Conditions	Temperature: 10 to 25 °C	Temperature: 10 to 30°C	Temperature: 18 to 28°C	Similar
	Relative Humidity: 30% to 75% (non-condensing)	Relative Humidity: 20% to 80% (non-condensing)	Relative Humidity: 10% to 90% (non-condensing)	Similar
	Atmospheric pressure range: 60kPa to 106 kPa	Atmospheric pressure range: 66kPa to 106 kPa	Atmospheric pressure range: 70kPA to 106kPa	Similar

Microwave Ablation Probe				
Features/ Characteristics	**Subject Device** IntelliBlate Microwave Ablation System and Accessories	**Predicate Device** Emprint Ablation System with Thermosphere Technology (K200796)	**Predicate Device** Neuwave Certus 140 2.45 GHz Ablation System and Accessories (K100744)	**Comparison**
Compatible Microwave Ablation Probe	Ximitry Probe Assembly	Microwave ablation antenna with Thermosphere™ Technology	Ablation probes include Models Certus^{LN}, Certus^{LK}, Certus^{SR} and Certus^{PR}	See below comparison of the features
Antenna Connections	Single cable bundles integrating power cable and coolant tubing (supply and return lines)	Separate power cable and coolant tubing (supply and return lines)	Single cable bundles integrating power cable and coolant tubing (supply and return lines)	Single cable bundle
Power Connection	Power cable connects directly to the console	Power Cable connects to a reusable cable that connects to the console	Power cable connects to a reusable Power Distribution Module (PDM) is used between the probe and console	Different set for connection
Antenna Coolant Delivery	Coolant delivery connection via an integrated Cassette	Coolant delivery connection via manual connection to external peristaltic pump	Coolant delivery connection via an integrated connector	Integrated coolant delivery circuit

Coolant Connection	Via spike to the coolant bag	Via spike to the coolant bag	Via gas fitting connection to 2 CO2 gas cylinders	Subject and predicate device (K200796) have the same coolant connection.
Cooling medium	Sterile water/ saline	Sterile saline	CO2 gas	Additional coolant option
Distal Tip configuration	Ceramic Trocar Tip	Ceramic Trocar tip	Ceramic Trocar tip	Same
Antenna shaft length(s)	15 cm, 20 cm, 27 cm	15 cm, 20 cm, 30 cm	6cm, 15cm, 20cm, 25cm	Variable lengths to supportsoft tissue ablations..
Antenna Shaft Diameter	13.5 G (2.3mm)	13 G (2.4mm)	13G, 15G, 17G	Subject device has a thinner shaft profile
Right Angle Probe	Yes	Yes	Yes	Same
Antenna Shaft Construction	Fiberglass	Fiberglass	Stainless steel	Same
Probe Thermocouple	3 integrated thermocouples at pre-defined locations on the shaft and 2 internal temperature sensors within the probe handle	1 internal temperature sensor with no thermocouples on the shaft	3 integrated thermocouples at pre-defined locations on the shaft	Multiple temperature sensors
Patient Contacting Components	Antenna shaft, tip, adhesive and depth guide are biocompatible	Antenna shaft, tip, adhesive and depth guide are biocompatible.	Antenna shaft & tip are biocompatible.	Same
Software	No	No	No	Same
Device Usage	Single-use, disposable	Single-use, disposable	Single-use, disposable	Same
Sterilization	ETO	ETO	ETO	Same
Packaging Configuration and Materials	Thermoform tray and retainer lid with a single Tyvek sterile barrier lid within a SBS (solid bleached sulfate) shelf carton box sealed with a tamper paper tape.	Thermoform tray and single Tyvek sterile barrier lid within a SBS (solid bleached sulfate) shelf carton box sealed with a tamper paper tape.	Thermoform tray and single Tyvek sterile barrier lid within a SBS (solid bleached sulfate) shelf carton box sealed with a tamper paper tape.	Same
Optional Accessories	Laser alignment disc and depth guide	Depth guide	No optional accessories	Additional optional accessories

VII. Performance Data:

1. Non-clinical Testing:

IntelliBlate Microwave Ablation System and its accessories underwent non-clinical testing to demonstrate the design and performance of the devices meet the established design criteria and are substantial equivalent to the predicate devices. The subject devices successfully completed functional, ablation performance ex-vivo tissues, reliability, usability, and electrical testing.

Substantial equivalence in performance between the subject and predicate device cleared via K200796 was demonstrated by side-by-side testing of the subject and predicate devices for ablation. The ex-vivo testing of the devices at single, double and track ablation settings in porcine liver, kidney and muscle demonstrate that the differences in design and system characteristics do not affect the ablation performance of the subject device in comparison to the predicate device.

2. Non-clinical Animal Testing:

Animal testing with IntelliBlate Microwave Ablation System and its accessories were completed in accordance with the United States Food and Drug Administration Good Laboratory Practice (GLP) Regulations, 21 CFR Part 58 and included:

- Acute GLP studies to validate usability and performance of the devices on porcine soft tissue models.

3. Literature Review:

Systematic literature review conducted in support of indications of use with the predicate device identified a total of 1,628 patients and 2,438 tumors included in the 23 publications. The outcome and complication rates summarized from the predicate device published literature is comparable to the meta-analyses reviewed. The meta-analyses contain published literature comparing various microwave ablation systems to radio-frequency ablation, cryoablation or surgical resection. The literature search strategy was based on an SLR approach; both SLR sections, per unique studies and published SLRs/ meta-analyses, suggested the safe and effective use of microwave ablation for the soft tissue coagulation (ablation) of tumors.

4. Sterilization:

Ximitry Probe Assembly is sterilized utilizing 100% ethylene oxide gas to ensure a minimum sterility assurance level of 10^{-6} in accordance with ISO 11135, ISO 10993-7, ISO 11138-1, ISO 11737-1 and ISO 11737-2.

5. Software, Cybersecurity, and Interoperability

Software verification was conducted in accordance with IEC 62304 – “Medical device software - Software life cycle processes” and FDA guidance “Content of Premarket Submissions for Device Software Functions.

Cybersecurity requirements were assessed per FDA guidance’s Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Postmarket Management of Cybersecurity in Medical Devices.

6. **Thermal Effects and Temperature Monitoring:**
   Thermal effects and temperature monitoring testing were completed in accordance with FDA Guidance - Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery.
   Comparison of thermal effects between IntelliBlate Microwave Ablation System and its predicate demonstrated that the performance of the subject device is substantially equivalent to the predicate device.

7. **Biocompatibility:**
   Biocompatibility testing of the Ximitry Probe Assembly in accordance with ISO 10993-1 demonstrated that the patient-contacting components are biocompatible.

8. **Electrical Safety and Electromagnetic Compatibility:**
   The IntelliBlate Microwave Ablation System and its accessories comply with applicable IEC 60601 series of standards: IEC 60601-1, IEC 60601-1-6, IEC 60601-2-6, and IEC 60601-1-2.

9. **Packaging Integrity and Shelf Life:**
   Packaging integrity and shelf-life testing was performed in accordance with ISO 11607-1 and ISO 11607-2.

VIII. Conclusion:

The subject device and predicate device(s) technological characteristics are equivalent. The nonclinical verification and validation performance data supports the safety and effectiveness of the subject device as indicated for use. Varian considers the IntelliBlate Microwave Ablation System and its accessories technological characteristics to be as safe and effective as the predicate device(s) and therefore, substantially equivalent to the predicate device(s).