April 23, 2024

Emblation Limited
℅ Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K240518
Trade/Device Name: swiftPro™ System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: February 21, 2024
Received: February 23, 2024

Dear Angela Blackwell:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.04.23 08:11:45 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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.

Submission Number *(if known)*

K240518

Device Name

swiftPro™ System

Indications for Use *(Describe)*

The swiftPro™ System is a surface-based device intended for the coagulation of soft tissue during non-invasive procedures.
The swiftPro™ System is not indicated 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.

510(k) Summary

The 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of 21 CFR Part 807.92.

I. SUBMITTER

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Contact Person: Mairi MacFadyen
Chief Regulatory Officer

Date Prepared: February 2, 2024

II. SUBJECT DEVICE

Name of Device	swiftPro™ System and Accessories
Common Name	Microwave ablation system and accessories
Classification Name	Electrosurgical Cutting & Coagulation Device and Accessories, 21 CFR 878.4400
Regulatory Class	II
Product Code	NEY

III. PREDICATE DEVICE

Name of Device	swiftPro™ System
Common Name	Microwave ablation system and accessories
510(k) Number	K222388
Classification Name	Electrosurgical Cutting & Coagulation Device and Accessories, 21 CFR 878.4400
Manufacturer	Emblation Limited
Regulatory Class	II
Product Code	NEY

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The core swiftPro™ System, comprising the hand-held microwave generator (SWF-HAN01), DC power cable (SWF–DCA01), cradle (SWF-CRA01), and applicator tips (SWF-AT02, SWF-AT03), has previously received FDA clearance under K222388. This new 510(k) application has been submitted to incorporate optional accessories: the Battery Pack (SWF-BAT01), Charging Dock (SWF-CHA01), and Charging Dock DC power adaptor (SWF-DCA02) for cordless operation.

The clinical functionality of delivering treatment via the swiftPro™ System remains unchanged. The only distinction is the introduction of an additional potential energy source. The power is supplied to swiftPro™ system by either a (external) medical-grade AC-DC adaptor with direct connection to the rear panel of the hand-held microwave generator or via a removable, rechargeable (optional) battery pack.

There haven't been any alterations to the design, or the material used in the swiftPro™ hand-held microwave generator. The operation of the subject device follows the same steps as the predicate device. The addition of the accessories does not have any effect on the mode of operation.

Battery Pack (SWF-BAT01)
The swiftPro™ system can be powered by a battery (SWF-BAT01) which is mounted internally and secured within the hand-held microwave generator during treatment. The batteries used in swiftPro™ are custom, Lithium-Ion Smart batteries, which contain internal protections to mitigate potential faults. Smart battery authentication has been integrated to ensure that only an authentic battery powers the swiftPro™ microwave generator.

Charging Dock (SWF-CHA01)
SwiftPro™ Charging Dock (SWF-CHG01) is designed to support the swiftPro™ system and charge the SWF-BAT01 Battery pack, either standalone, or when contained within the SWF-HAN01 hand-held microwave generator. SwiftPro™ Charging Dock can be used as an alternative power source for the system other than the swiftPro™ AC-DC desktop adapter SWFDC01. The charging dock also has a slot or "bay" with charging connections for a spare battery underneath the swiftPro™. The Charging Dock does not have any clinical function, any patient interactions nor any applied parts.

Table below provides a list of components comprising the swiftPro™ System and its accessories.

swiftPro™ System			
Product Code	**Product Name**	**Description**	**Previously cleared 510 (k) Number**
SWF-MIC01	swiftPro™ hand-held treatment system	A hand-held system containing SWF-HAN01 and SWF-DCA01.	K222388
SWF-HAN01	swiftPro™ hand-held microwave generator	A hand-held microwave generator containing the microwave amplifier and software-controlled display.	K222388
SWF-DCA01	swiftPro™ DC power adaptor	A medical grade isolated power supply.	K222388
Accessories			
SWF-CRA01	swiftPro™ Cradle	A table-top cradle to rest the hand-held treatment system on when not in use.	K222388
SWF-AT02	swiftPro™ URT Applicator Tip	A disposable applicator which includes device identification, re-use mitigation and a biological barrier.	K222388
SWF-AT03	swiftPro™ LRT Applicator Tip	A disposable applicator which includes device identification, re-use mitigation and a biological barrier.	K222388
Optional Accessories			
SWF-BAT01	swiftPro™ Battery Pack	Removable, rechargeable battery pack provides an alternative means of power to the SWF-HAN01.	-
SWF-CHA01	swiftPro™ Charging Dock	The swiftPro™ Charging Dock is a table-top rest for the swiftPro™ hand-held microwave generator and provides a charging interface for the SWF-BAT01 Battery Pack which may be charged either as a standalone item or when it is installed within SWF-HAN01.	-
SWF-DCA02	swiftPro™ Charging Dock DC power adaptor	A medical grade isolated power supply used to provide power to the Charging Dock.	-

V. INDICATIONS FOR USE

The swiftPro™ System is a surface-based device intended for the coagulation of soft tissue during non-invasive procedures.
The swiftPro™ System is not indicated for use in cardiac procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The swiftPro™ hand-held microwave generator (SWF-HAN01), is identical to that used in the predicate device (K222388), therefore maintains the same technological characteristics in terms of materials and design. The existing applicator/antenna design delivers the same frequency and magnitude of microwave energy to target tissues in a controlled manner, serving the same intended purpose as the predicate.

The only technological distinction in the hand-held microwave generator (SWF-HAN01) lies in the introduction of an additional potential energy source. While the swiftPro™ System now offers the option of being powered by a battery and charging dock, it still retains the capability to be charged via the mains power cable.

While the option to power the swiftPro™ System via battery introduces different technological characteristics due to the energy source, it does not raise additional questions regarding safety and effectiveness. The clinical functionality of delivering treatment via the swiftPro™ System remains unchanged. The indication for use is the same with that of the predicate device. Non-clinical bench testing has demonstrated that the technological differences do not affect device performance. Performance data is provided to establish substantial equivalence with the predicate device.

SwiftPro™ Hand-held Microwave Generator

The hand-held microwave generator, is identical to that used in the predicate device, therefore maintains the same technological characteristics in terms of materials and design.

SwiftPro™ Applicator Tip

The functionality and material composition of the applicator tips have not undergone any changes between the predicate and subject device.

Comparison Table

Device Feature	swiftPro™ System and Accessories (Subject)	swiftPro™ System (Predicate)	Comments
510(k) Number	Unknown	K222388	N/A
Classification Regulation 21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Identical
Product Code	NEY	NEY	Identical
510(k) Holder/ Manufacturer	Emblation Limited	Emblation Limited	Identical
Indications for Use	The swiftPro™ System is a surface-based coagulation of soft tissue during non-invasive procedures. The swiftPro™ System is not indicated for use in cardiac procedures.	The swiftPro™ System is a surface-based coagulation of soft tissue during non-invasive procedures. The swiftPro™ System is not indicated for use in cardiac procedures.	Identical

Dimensions Width x Height x Depth	Hand-held Microwave Generator: 245x75x135mm (10x3x5.3 inch) Additional accessories have the following dimensions: Charging Dock: 305 x 95 x 110 mm (12 x 3.8 x 4.4 inches) Battery Pack: 105 x 30 x 65 mm (4.2 x 1.2 x 2.6 inches)	Hand-held Microwave Generator: 245x75x135mm (10x3x5.3 inch)	Identical – the dimensions of the hand-held microwave generator are unchanged. New – Charging Dock and Battery Pack dimensions added.
Weight	Hand-held Microwave Generator: Less than 0.75kg (∽1.65lbs) Additional accessories have the following weight: Charging Dock: Less than 0.8 kg (~1.75 lbs) Battery Pack: Less than 0.25 kg (~0.55 lbs)	Hand-held Microwave Generator: Less than 0.75kg (∽1.65lbs)	Identical – the weight of the hand-held microwave generator is unchanged. New – Weight of the Charging Dock and Battery Pack added.
Material	Enclosure Material: Handpiece - ABS/PC CYCOLOY™ Resin HC1204HF Applicator Tip material: ABS/PC CYCOLOY™ Resin HC1204HF Biobarrier material – SILPURAN® 6000/70 Liquid Silicone Rubber The enclosure of the additional accessories, including the charging dock and battery pack, is manufactured from the same material (Cycoloy HC1204 HF Resin) as the hand-held microwave generator and applicator tips.	Enclosure Material: Handpiece - ABS/PC CYCOLOY™ Resin HC1204HF Applicator Tip material: ABS/PC CYCOLOY™ Resin HC1204HF Biobarrier material – SILPURAN® 6000/70 Liquid Silicone Rubber	Identical New accessories are manufactured using the same material as the hand-held microwave generator and applicator tips.
Generator	Yes	Yes	Identical

Energy	Microwave Mains Power and/or Battery	Microwave Mains Power	Same frequency and magnitude of microwave energy is delivered to target tissues. An additional energy source battery option is added.
Maximum Microwave Power	0-10 in 1power level increments = treatment, 6W = Generator Tip ATO2 restricts delivered energy to 6W output (corresponds to power level setting of 10)	0-10 in 1power level increments = treatment, 6W = Generator Tip ATO2 restricts delivered energy to 6W output (corresponds to power level setting of 10)	Identical
Isolation	BF	BF	Identical
Time settings	0-10 secs	0-10 secs	Identical
Max coagulation cycle	15-20 minutes but treatment dependant & limited by applicator tip used to 10 seconds max.	15-20 minutes but treatment dependant & limited by applicator tip used to 10 seconds max.	Identical
Vacuum	No	No	Identical
Shut Offs/ Alarms	Alerts: MSM overtemp, Expired tip, No applicator detected, Reflection, Manual Switch Status System error, SD Card Error, Service error, Now includes; low battery, battery error	Alerts: MSM overtemp, Expired tip, No applicator detected, Reflection, Manual Switch Status System error, SD Card Error, Service error	The low battery and battery error functions, previously present in the predicate hand-held microwave generator, have now been activated. If an error is detected with the battery, an Error indicator will flash orange.
Software/ Firmware Platform	Yes	Yes	Both the application software and firmware have been updated to accommodate minor improvements for the charging dock and battery pack elements.
Hardware control	Yes	Yes	Same

Monitored parameters	Power, Time, Reuse status, Applicator connected Reflected power Now includes; Battery Charge	Power, Time, Reuse status, Applicator connected Reflected power	Battery charge indicator has been added. When a battery pack is connected to swiftPro™, this section shows the charge level of the connected battery.
Display parameters	Set Power (Unit 1-10) Set Time/Treatment Time (secs), Settings Menu Device Information Screen Brightness Selection Auto/Manual Mode Selection Set Time and Date Recall Treatment Menu	Set Power (Unit 1-10) Set Time/Treatment Time (secs), Settings Menu Device Information Screen Brightness Selection Auto/Manual Mode Selection Set Time and Date Recall Treatment Menu	Identical
Manual or automatic setting	Manual or Automatic can be selected.	Manual or Automatic can be selected.	Identical
Operation Mode	PWM & fixed frequency	PWM & fixed frequency	Identical
Surface Applicator/ Antenna	Surface Applicator	Surface Applicator	Identical
Patient contact part supplied sterile	No – Patient contact parts supplied non-sterile (disposable applicator tips)	No – Patient contact parts supplied non-sterile (disposable applicator tips)	Identical
Applicator/ Antenna Design	Ceramic waveguide Disposable silicone barrier	Ceramic waveguide Disposable silicone barrier	Identical
Applicator/ Antenna head Size	Applicator Tip approximately 4 cm x 3 cm Silicone/Ceramic contact face 6.7 mm diameter	Applicator Tip approximately 4 cm x 3 cm Silicone/Ceramic contact face 6.7 mm diameter	Identical
Applicator/ Antenna Use	Soft tissue coagulation	Soft tissue coagulation	Identical
Rigid shaft	Yes	Yes	Identical
Footswitch	No	No	Identical

Tissue Temp monitoring	N/A	N/A	N/A
Max applicator surface Temp (non-active areas)	42°C	42°C	Identical
Operation Procedure	Surface use	Surface use	Identical
Average energy density of surface application (Area J/mm2)	10 J/mm2 Set power level 10 Set time 1 Seconds 6J delivered	10 J/mm2 Set power level 10 Set time 1 Seconds 6J delivered	Identical
Electrical 60601 & EMC Compliant	Yes	Yes	The additional accessories comply with the requirements of electrical safety and IEC 60601.
IP Rating	IP20	IP22	Different, IP22 rating not required for professional healthcare facility.
Biocompatible	Yes	Yes	SWF-BAT01 swiftPro™ Battery Pack – is not designed to come in contact with patients. It's made from the material Cycoloy HC1204 HF Resin, which is biocompatible and the same material used in the hand-held microwave generator & Applicator Tip. SWF-CHG01 SwiftPro™ Charging Dock – is not designed to come in contact with patients. It's made from the material Cycoloy HC1204 HF Resin, complies with biocompatibility standards ISO10993 and the same material used in the hand-held microwave generator & Applicator Tip.

VII. PERFORMANCE DATA

The following performance data were provided in support of substantial equivalence determination, using the either the same or similar methods and information used for the predicate device.

Biocompatibility testing

Biocompatibility testing in accordance with ISO10993: Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process was performed:

- Cytotoxicity
- Sensitisation
- Irritation
- Systemic toxicity
- Pyrogenicity

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted and the swiftPro™ system and accessories comply with all the applicable Medical electrical equipment standards for safety and essential performance.

- IEC 60601-1:2005 + AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-2-6: 2012 + AMD1:2016 Medical electric equipment Part 2: Particular requirements for basic safety and essential performance of microwave therapy equipment.
- IEC 60601-1-2:2014 +AMD1:2020 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances-Requirements and tests.
- IEC 62133-2:2017+AMD1:2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Software Verification and Validation Testing

The application of software and firmware for the SwiftPro™ system has been updated to accommodate the use of the battery pack and charging for system power, in accordance with IEC 62304:2006 (AMD1: 2015) and FDA guidance for software contained in medical devices.

Cybersecurity

The swiftPro™ system and accessories are not intended to be used as a networked medical device, nor do they contain any off-the-shelf (OTS) software to support connection to a private or public internet. The swiftPro™ system and accessories do not incorporate an OTS operating system or OTS software/drivers which supports hard-wired or wireless network connections. Throughout the lifecycle of the device, an assessment to mitigate cybersecurity vulnerabilities has been completed.

Human Factors and Usability Engineering

The swiftPro™ system and accessories comply with all the applicable requirements of the following standards:

- ANSI/ AAMI HE75:2009/R2013 American National Standard / Association for the Advancement of Medical Instrumentation. Human Factors Engineering – Design of Medical Devices
- IEC 60601-1-6:2010+AMD1:2013 +AMD2:2020, Medical electrical equipment – General requirements for basic safety and essential performance. Collateral standard: Usability
- IEC 62366-1:2015+AMD1:2020 Medical Devices. Application of Usability Engineering to Medical Devices
- FDA-2011-D-0469 Applying Human Factors and Usability Engineering to Medical Devices.

Bench Testing
An evaluation of the performance equivalence of the swiftPro™ device was conducted, using the different power supply options available. Bench testing involved assessing the performance equivalence of the device when powered by the battery and wired options in ex vivo tissue. Additionally, an assessment of the impact of battery charge levels on the performance of the swiftPro™ device was carried out. The CN-901 CAIRN Power Source Bench Equivalence Test Report assesses performance at various charge levels.

The bench testing proves the swiftPro™ System and Accessories performs substantially equivalent to the predicate device.

VIII. CONCLUSIONS

The swiftPro™ System and Accessories are considered equivalent to the predicate device, swiftPro™ System, K222388. The intended use, specifications and associated performance testing and data provided in this submission are sufficient to demonstrate this fact.

The subject device is operated in the same manner as the predicate, within the identical intended use case and environment, which have been deemed safe and effective.