May 4, 2023

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

Re: K222388
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: April 3, 2023
Received: April 4, 2023

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 (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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.04 08:54:38 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222388

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 MacFayden
Chief Regulatory Officer

Date Prepared: May 2, 2023

II. DEVICE

Name of Device:	swiftPro® System
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

Trade Name:	Swift® System
Common Name:	Microwave ablation system and accessories
510(k) Number	K181941
Manufacturer:	Emblation Limited
Regulatory Class	II
Product Code:	NEY

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

IV. DEVICE DESCRIPTION

The swiftPro® system is the subject of this application and is substantially equivalent to the device described and cleared in K181941, the subject device is an all-encompassing version of the Swift® System.

The swiftPro® system is a hand-held microwave generator intended to provide the functionality of the Swift® microwave treatment system in a compact and portable package. The system comprises a hand-held microwave generator and an applicator tip assembly. The generator produces microwave energy at a frequency of 8 GHz with a maximum output power of 6 Watts, the output power is restricted depending on the applicator tip attached, which delivers the microwave energy to the tissue to effect thermal heating.
The swiftPro® System interface is intuitive with a quick setup for setting treatment; output power level & treatment duration (seconds). The applicator tip and the handheld generator have been designed to be only connected in a certain way with a single, simple connection mechanism. This prevents the possibility of system malfunction due to incorrect setup or confusion. The SwiftPro® applicator tips have been designed to prevent re-use to mitigate the risk of cross-contamination.

The SwiftPro® system compromises of the following components:

- SwiftPro® Handheld Generator
- SwiftPro® Cradle
- SwiftPro® URT Applicator tip (non-sterile, single use)
- SwiftPro® LRT Applicator tip (non-sterile, single use)

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

Microwave coagulation is the technological principle for both the swiftPro® System and predicate device. It is based on the use of microwave energy for the coagulation of soft tissue, where the user has the ability to select the desired power and time limits based on size of the target area.

The technological characteristics are the same regarding frequency and magnitude of microwave energy delivered to a target tissue through the existing applicator/antenna design as used in the existing Swift® System (predicate) in a controlled manner for the purpose of coagulation of soft tissue. The main differences relate to the addition of FPGA firmware and a software user interface which replicates the core experience (treatment power/time settings and a single button to enable/disable energy deposition) of using the existing Swift device.

The operation of the swiftPro® user interface is controlled via device-embedded software, responsible for handling user inputs and providing system status indications. Microwave control and functionality and system safety is provided by firmware. Both the application software and firmware are installed on devices located on the System Controller Module (microcontroller IC and FPGA respectively). However, both the subject device and predicate have hardware or firmware (FPGA) based safety controls, the addition of software controls relates purely to improve user experience.

The predicate device operation is controlled by a digital logic state machine which, by its nature, requires a high number of components to implement for this approach to be capable of providing the level of functionality required. This component count requires a number of large PCBAs – and interconnecting components – to support, and therefore results in a large system footprint and high cost.

The swiftPro® system replicates this functionality through use of embedded software and FPGA firmware, significantly reducing the system real estate consumed by PCBAs and their peripherals and allows for a high degree of compact integration in the system architecture. The inclusion of software and firmware within the design also permits the system functionality to be enhanced, and results in further streamlining of the system by permitting a graphical user interface (GUI) to be implemented, removing the need for discrete LED indicators as present in the Swift® system. The GUI has been designed to replicate the experience of using the existing swift® device.

SwiftPro® Handheld Generator Treatment System
The swiftPro® handheld generator is constructed from control PC-ABSs which are the same biocompatible materials as the applicator tip with an integrated user interface. Includes functional indicators, display auditory feedback, and programmable system control capability. The handheld generates microwave power up to 6W using hardware controlled internally regulated microwave source. The output signal from the SwiftPro™ generator is provided by the integrated user interface. The output power can be varied from 1W increments to 6W using pulse width modulation (PWM) techniques. This provides regulated microwave energy at a central frequency of 8GHz and provides real-time reflected power monitoring which ensures that the treatment is progressing as normal and that the handheld generator is performing as expected.

The swiftPro® System does not require a handpiece or cable to operate as it is an all-encompassing device and this is the main reason for the device weighing less and smaller than the predicate device. The design is different from the predicate device but the differences do not affect the fundamental principles of technology.

SwiftPro® Applicator Tip
The swiftPro® Applicator tip is identical to the predicate in design and materials used. There are no technological differences. The swiftPro® Applicator Tips are mechanically, physically, and electrically identical to the Swift® SWF-AT01 Applicator Tip, differing only in the value of resistor fitted to their (internal) PCBA which denotes the Tip DUID.

Comparison Table

Device Feature	swiftPro® System	Swift® System (Predicate)	Comments
Classification Regulation 21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Product Code	NEY	NEY	Same
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.	The Swift® System is a surface-based device intended for the coagulation of soft tissue during non-invasive procedures. The Swift® System is not indicated for use in cardiac procedures.	Same
Dimensions Width x Height x Depth	245x75x135mm (10x3x5.3 inch)	300x90x300mm (11.8x3.5x11.8 inch)	Different, the subject device is smaller
Weight	Less than 0.75kg (~1.65lbs)	Less than 4.5kg (~10 lbs)	Different, the subject device is lighter
Material	Enclosure Material: Handpiece - ABS/PC CYCOLOY™ Resin HC1204HF Tip material: ABS/PC CYCOLOY™ Resin HC1204HF Biobarrier material – SILPURAN® 6000/70 Liquid Silicone Rubber	Enclosure Material: Handpiece - ABS/PC CYCOLOY™ Resin HC1204HF Generator - Aluminium Interconnect Cable- Silicone Rubber TEKBOND TB1723 Tip material - ABS/PC CYCOLOY™ Resin HC1204HF Biobarrier material – SILPURAN® 6000/70 Liquid Silicone Rubber	Different but as detailed where there is analogy between the devices they are constructed from the same material
Power Supply	24Vdc	90-645Vac	Different, the subject device requires lower power and can use a low voltage dc adaptor
Generator	Yes	Yes	Same
Energy	Microwave	Microwave	Same
Microwave Output Frequency	8 GHz	8 GHz	Same
Maximum Microwave Power	0-10 in 1power level increments = treatment, 6W = Generator Tip ATO2 restricts delivered energy to 6W output (corresponds to a power	0-10W in 1W increments = treatment, 20W = Generator Tip ATO1 restricts delivered energy to 6W output (corresponds to a 10W	Different, but as detailed swiftPro® performs within the equivalent AT01 (predicate) output

	level setting on generator of 10)	generator setting)	range.
Time settings	0-10 secs	0-10 secs	Same
Coagulation cycle	Maximum 15 minutes but treatment dependant & limited by applicator tips (AT02 and AT03).	Maximum 15 mins but treatment dependant & limited by applicator (AT01).	Different, two tip (AT02 and AT03) options to segregate energy delivery.
Shut Offs/ Alarms	Alerts: MSM overtemp, Expired tip, No applicator detected, Reflection, Manual Switch Status System error, SD Card Error, Service error	Alerts: MSM overtemp, Expired tip, No applicator detected, Reflection, Continuous wave/Swept Manual Switch Status System error	Existing alerts & descriptive Icons have been reused. Additional alerts have been incorporated into swiftPro® System for expanded functionality.
Software/ Firmware Platform	Yes	No	Addition of FPGA firmware and a software user interface
Hardware control	Yes	Yes	Same, implemented in FPGA firmware
Monitored parameters	Power, Time, Reuse status, Applicator connected Reflected power	Power, Time, Reuse status, Applicator connected Reflected power	Expanded parameters based on additional system functions.
Display parameters	Set Power (1-10 units) Set Time/Treatment Time (secs), Settings Menu Alerts Device Information Screen Brightness Selection Auto/Manual Mode Selection Set Time and Date Recall Treatment Menu	Set Power (1 -10 Watts) Set Time/Treatment Time (mins/secs), Actual power delivered (% of set), Alerts	Different due to power setting unit change but having equivalent output. As with the predicate device, the system monitors its own applied and reflected power and will display an alert in the event of a trip.
Manual or automatic setting	Manual or Automatic can be selected.	Manual or Automatic, via (footswitch) can be selected.	Same, excludes footswitch as was never utilised in the market
Operation Mode	PWM & fixed frequency	PWM/& Swept	Different due to fixed frequency
Surface Applicator/ Antenna	Surface Applicator	Surface Applicator	Same
Patient contact part supplied sterile:	Non-sterile disposable applicator tip	Non-sterile disposable applicator tip	Same
Applicator/ Antenna Design	Ceramic waveguide Disposable silicone barrier	Ceramic waveguide Disposable silicone barrier	Same
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 Cable constructed of coaxial cable Handpiece approximately 12 cm x 3 cm	Same Applicator/ Antenna head size but system no longer incorporates a separate handpiece and interconnect cable
Max applicator surface Temp (non-active areas)	42°C	42°C	Same
Operation Procedure	Surface use	Surface use	Same
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 10W Set time 1 Seconds 10Jset, 6J delivered	Same (in terms of energy delivered)

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

The applicator tips were subject to biocompatibility testing, the swiftPro® System uses the same type of applicator tip as the predicate and the following Biocompatibility tests were completed in accordance with ISO10993: Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process:

- Cytotoxicity
- Sensitisation
- Irritation
- Systemic toxicity
- Pyrogenicity

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted and the swiftPro® system complies 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 60601-1-11:2015 Medical electrical equipment – Part1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- 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.

Software Verification and Validation Testing

The swiftPro® System includes embedded software which has been developed for use with an STM32 device, which incorporates a 32-bit ARM Cortex-M4 microcontroller. The embedded software produced for the swiftPro™ System includes source code, object files, executable load images, and all software documentation required for compliance with IEC 62304:2006 (AMD1: 2015) and FDA guidance for software contained in medical devices.

Cybersecurity

The swiftPro® system is not intended to be used as a networked medical device, nor does it contain any off-the-shelf (OTS) software to support connection to a private or public internet. The device does not incorporate an OTS operating system or OTS software/drivers which supported hard-wired or wireless network connections. Throughout the lifecycle of the product, an assessment to mitigate cybersecurity vulnerabilities has been completed. The following have been documented:

- Software Bill of Materials
- Threat Modelling
- Total Product Lifecycle
- Security Architecture
- Cybersecurity Testing
- Labelling

Human Factors and Usability Engineering
The swiftPro® system complies 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
Equivalence bench testing, including ex-vivo, within a common subset of settings has been performed to assess the common performance equivalence of the swiftPro® handheld system in comparison to the predicate device (K181941). The bench testing proves the swiftPro® System performs substantially equivalent to the predicate device.

- Thermal effects analysis in ex-vivo porcine skin
- Thermal effects analysis in ex-vivo bovine liver, porcine kidney and porcine muscle

VIII. CONCLUSIONS

The difference between the subject device (swiftPro® System) and the predicate device (Swift® System) technological characteristics do not raise any new or different questions regarding safety and effectiveness. The performance testing demonstrates the subject device is as safe and effective as the predicate device as indicated for use.