



August 8, 2025

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

Re: K250718

Trade/Device Name: swiftPro System (SWF-SPS); Swift System (SWF-SYS)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: July 8, 2025
Received: July 9, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

 Julie A.
Morabito -S

Julie Morabito, Ph.D.

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

Indications for Use

510(k) Number (if known)
K250718

Device Name
swiftPro System
Swift System

Indications for Use (Describe)

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 genital warts or cardiac procedures.

Specific Indication: Treatment of Common and Plantar Warts.

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 genital warts or cardiac procedures.

Specific Indication: Treatment of Common and Plantar Warts.

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.

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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

Emblation Limited
Emblation House, Castle Business Park
Stirling, FK9 4TS, UK

Phone: +44(0) 1786 657 204

Contact Person: Jack Ozer
Regulatory Manager

Date Prepared: February 6, 2025

II. SUBJECT DEVICES

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

Name of Device	Swift™ 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 DEVICES

Name of Device	swiftPro™ System and Accessories
Common Name	Microwave ablation system and accessories
510(k) Number	K240518
Classification Name	Electrosurgical Cutting & Coagulation Device and Accessories, 21 CFR 878.4400
Manufacturer	Emblation Limited
Regulatory Class	II
Product Code	NEY

Name of Device	Swift™ System
Common Name	Microwave ablation system and accessories
510(k) Number	K181941
Classification Name	Electrosurgical Cutting & Coagulation Device and Accessories, 21 CFR 878.4400
Regulatory Class	II
Product Code	NEY

The predicate devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Swift™ System is a microwave-based system intended to delivery energy through a surface contact applicator into targeted soft tissue for the purpose of coagulating (ablation) a pre-defined volume of tissue. The Swift™ System serves as a predicate device to the swiftPro™ System, which was originally cleared under 510(k) K222388. The swiftPro™ System is a handheld microwave generator designed to provide the same functionality as the Swift™ System in a more compact package.

The Swift™ System (SWF-SYS) consists of the following components:

- Swift™ Microwave Generator (SWF-GE01)
- Swift™ Applicator Handpiece (SWF-HP01)
- Swift™ Interconnect Cable (SWF-CA01)
- Swift™ Applicator Tip (SWF-AT01)

The Swift™ System was previously cleared under 510(k) K181941.

The swiftPro™ System (SWF-SPS) consists of the following components:

- swiftPro™ Handheld Microwave Generator (SWF-HAN01)
- swiftPro™ DC Power Cable (SWF-DCA01)
- swiftPro™ Cradle (SWF-CRA01)
- swiftPro™ Applicator Tips (SWF-AT02, SWF-AT03)

The swiftPro™ System was initially cleared under 510(k) K222388 and subsequently received updated clearance under K240518 to include the swiftPro™ Charging Dock (SWF-CHA01) and Battery Pack (SWF-BAT01) for cordless operation.

There have been no modifications to the design, principles of operation, or materials used in the Swift™ and swiftPro™ Systems. The clinical functionality of delivering treatment remains unchanged.

The table below provides a list of components included in the Swift™ and swiftPro™ Systems.

Swift™ System (SWF-SYS)			
Product Code	Product Name	Description	510(k) Number(s)
SWF-GE01	Swift™ Microwave Generator	The Swift microwave generator is intended to be used with the Swift applicator for the coagulation of soft tissue.	K181941
SWF-HP01	Swift™ Applicator Handpiece	The Swift applicator handpiece connects to the Swift microwave generator via the Swift interconnect cable.	K181941
SWF-CA01	Swift™ Interconnect Cable	The Swift interconnect cable connects the Swift handpiece with the Swift microwave generator.	K181941
SWF-AT01	Swift™ Applicator Tip	Swift applicator tip is provided as a single-use, non-sterile disposable tip, which is connected to the Swift handpiece.	K181941
swiftPro™ System (SWF-SPS*)			
Product Code	Product Name	Description	510(k) Number(s)
SWF-HAN01	swiftPro™ hand-held microwave generator	A hand-held microwave generator containing the microwave amplifier and software-controlled display.	K240518, K222388
SWF-DCA01	swiftPro™ DC power adaptor	A medical grade isolated power supply.	K240518, K222388

SWF-CRA01	swiftPro™ Cradle	A table-top cradle to rest the hand-held treatment system on when not in use.	K240518, K222388
SWF-AT02	swiftPro™ URT Applicator Tip	A disposable applicator which includes device identification, re-use mitigation and a biological barrier.	K240518, K222388
SWF-AT03	swiftPro™ LRT Applicator Tip	A disposable applicator which includes device identification, re-use mitigation and a biological barrier.	K240518, K222388
SWF-BAT01	swiftPro™ Battery Pack	Removable, rechargeable battery pack provides an alternative means of power to the SWF-HAN01.	K240518
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.	K240518
SWF-DCA02	swiftPro™ Charging Dock DC power adaptor	A medical grade isolated power supply used to provide power to the Charging Dock.	K240518

* SWF-SPS is a bundled SKU of the full swiftPro System (SWF-MIC01 & SWF-BPS01). SWF-MIC01 is the ordering SKU for the swiftPro System including the SWF-HAN01, SWF-DCA01 and SWF-CRA01. SWF-BPS01 is the ordering SKU for the swiftPro Battery Power System including the SWF-CHA01, 2 X SWF-BAT01 and SWF-DCA02.

V. INDICATIONS FOR USE

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 genital warts or cardiac procedures.

Specific Indication: Treatment of common and plantar warts.

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 genital warts or cardiac procedures.

Specific Indication: Treatment of common and plantar warts.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Swift™ and swiftPro™ Systems are identical to their predicate devices, swiftPro™ (K240518) and Swift™ (K181941), maintaining the same technological characteristics. Both systems achieve the same intended use, with the addition of the treatment of common and plantar warts to their Indications for Use. The clinical functionality of delivering treatment via the Swift™ and swiftPro™ Systems remains unchanged.

The functionality and material composition of the Swift™ and swiftPro™ System components have not undergone any changes between the predicate and subject devices. The Swift™ System received FDA clearance under K181941. The swiftPro™ System initially received FDA clearance under K222388, and subsequently obtained updated clearance under K240518 to include the charging dock and batteries for cordless operation.

The addition of a specific indication for the treatment of common and plantar warts does not raise different questions regarding safety or effectiveness. To support the expanded indications for use, a pivotal,

randomised, multi-site, open, parallel-group, controlled, blind-assessed clinical study was conducted comparing the Swift™ System to cryotherapy, which is currently considered the gold standard for treating common and plantar warts. The cryotherapy device used for comparison in the study was the Cry-Ac B700 (Brymill), an FDA-cleared device (K193619) with indications for use that include the treatment of common and plantar warts.

The objective of the clinical study was to collect definitive safety and effectiveness evidence for the use of microwave energy in the treatment of common and plantar warts. The study results demonstrated that the Swift™ System is safe and effective for this expanded indication and that its safety profile was comparable to the Brymill Cry-Ac B700 cryotherapy device. No new risks were identified that have not been previously considered or assessed, and the treatment outcomes were consistent with those observed in prior clinical use.

Substantial Equivalence Comparison Table: Swift™ System

Device Feature	Swift System (Subject Device)	Swift System (Predicate Device)	Comments
510(k) Number	K250718	K181941	N/A
Legal Manufacturer	Emblation Limited	Emblation Limited	Identical
Indications for Use	<p>The Swift™ System is a surface based device intended for the coagulation of soft tissue during non-invasive procedures.</p> <p>The Swift™ System is not indicated for use in genital warts or cardiac procedures.</p> <p>Specific Indication: Treatment of common and plantar warts.</p>	<p>The Swift™ System is a surface based device intended for the coagulation of soft tissue during non-invasive procedures.</p> <p>The Swift™ System is not indicated for use in cardiac procedures.</p>	<p>Similar</p> <p>Statement added indicating the Swift System is not for use on genital warts.</p> <p>A specific Indications for Use statement has been added to include 'treatment of common and plantar warts'.</p> <p>The addition of this indication does not introduce new risks. There are no changes to the design or technological characteristics of the device. The clinical application of the Swift™ System remains unchanged.</p>
Dimensions Width x Height x Depth	300x90x300mm (11.8x3.5x11.8 inch)	300x90x300mm (11.8x3.5x11.8 inch)	Identical
Weight	Less than 4.5kg (~10 lbs)	Less than 4.5kg (~10 lbs)	Identical
Material	<p><u>Swift Enclosure Material</u> Handpiece: ABS/PC CYCOLOY™ Resin HC1204HF Tip material: ABS/PC CYCOLOY™ Resin HC1204HF Biobarrier material: SILPURAN® 6000/70 Liquid Silicone Rubber Generator: Aluminium Interconnect Cable: Silicone Rubber TEKBOND TB1723*</p>	<p><u>Swift Enclosure Material</u> Handpiece: ABS/PC CYCOLOY™ Resin HC1204HF Tip material: ABS/PC CYCOLOY™ Resin HC1204HF Biobarrier material: SILPURAN® 6000/70 Liquid Silicone Rubber Generator: Aluminium Interconnect Cable: Silicone Rubber TEKBOND TB1723*</p>	Identical
Energy	Microwave	Microwave	Identical

	Mains Power	Mains Power	
Maximum Microwave Power	0-10W in 1W increments = treatment, 20W = Generator Tip ATO1 restricts delivered energy to 6W output (corresponds to a 10W generator setting)	0-10W in 1W increments = treatment, 20W = Generator Tip ATO1 restricts delivered energy to 6W output (corresponds to a 10W generator setting)	Identical
Isolation	BF	BF	Identical
Time settings	0-10 secs	0-10 secs	Identical
Tip usable lifetime	15 mins	15 mins.	Identical
Coagulation cycle	10 seconds	10 seconds	Identical
Vacuum	No	No	Identical
Shut Offs/ Alarms	Alerts: MSM overtemp, Expired tip, No applicator detected, Reflection, Continuous wave/Swept Manual Switch Status System error	Alerts: MSM overtemp, Expired tip, No applicator detected, Reflection, Continuous wave/Swept Manual Switch Status System error	Identical
Software/ Firmware Platform	No	No	Identical
Hardware control	Yes	Yes	Identical
Monitored parameters	Power, Time, Reuse status, Applicator connected Reflected power Set Power (Watt) Set Time/Treatment Time (mins/secs), Actual power delivered (% of set), Alerts: - (start, auto/Manual, trips)	Power, Time, Reuse status, Applicator connected Reflected power Set Power (Watt) Set Time/Treatment Time (mins/secs), Actual power delivered (% of set), Alerts: - (start, auto/Manual, trips)	Identical
Display parameters	Set Power (Watt) Set Time/Treatment Time (mins/secs), Actual power delivered (% of set), Alerts: - (start, auto/Manual, trips)	Set Power (Watt) Set Time/Treatment Time (mins/secs), Actual power delivered (% of set), Alerts: - (start, auto/Manual, trips)	Identical
Manual or automatic	Manual or Automatic, via (footswitch) can	Manual or Automatic, via (footswitch)	Identical

setting	be selected.	can be selected.	
Operation Mode	PWM/& Swept	PWM/& Swept	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 Cable constructed of coaxial cable Handpiece approximately 12 cm x 3 cm	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	Identical
Applicator/ Antenna Use	Soft tissue coagulation	Soft tissue coagulation	Identical
Rigid shaft	Yes	Yes	Identical
Footswitch	Yes (optional)	Yes (optional)	Identical
Tissue Temp monitoring	N/A	N/A	Identical
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/mm ²)	10 J/mm ² Set power 10W/1 Seconds AT01 10Jset, 6J delivered	10 J/mm ² Set power 10W/1 Seconds AT01 10Jset, 6J delivered	Identical
Electrical 60601 & EMC Compliant	Yes	Yes	Identical
Biocompatible	Yes	Yes	Identical
Software and Cybersecurity	N/A - The Swift System does not have a software function.	N/A - The Swift System does not have a software function.	Identical
Human Factors and Usability Engineering	The Swift Systems comply with the requirements of all applicable Human Factors and Usability standards.	The Swift Systems comply with the requirements of all applicable Human Factors and Usability standards.	Identical
Electrical	Tested for compliance against	Electrical safety and EMC	Similar, see below

Safety and EMC Testing	the full scope of IEC 60601-1-2:2014/AMD1:2020.	testing were conducted, and the Swift System complies with all applicable Medical electrical equipment standards for safety and essential performance	
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Substantial Equivalence Comparison Table: swiftPro™ System

Device Feature	swiftPro System (Subject Device)	swiftPro System (Predicate Device)	Comments
510(k) Number	K250718	K240518	N/A
Legal Manufacturer	Emblation Limited	Emblation Limited	Identical
Indications for Use	<p>The swiftPro™ System is a surface based device intended for the coagulation of soft tissue during non-invasive procedures.</p> <p>The swiftPro™ System is not indicated for use in genital warts or cardiac procedures.</p> <p>Specific Indication: Treatment of common and plantar warts.</p>	<p>The swiftPro™ System is a surface based device intended for the coagulation of soft tissue during non-invasive procedures.</p> <p>The swiftPro™ System is not indicated for use in cardiac procedures.</p>	<p>Similar</p> <p>Statement added indicating the swiftPro System is not for use on genital warts.</p> <p>A specific Indications for Use statement has been added to include 'treatment of common and plantar warts'.</p> <p>The addition of this indication does not introduce new risks. There are no changes to the design or technological characteristics of the device. The clinical application of the swiftPro™ System remains unchanged.</p>
Dimensions Width x Height x Depth	<p>Hand-held Microwave Generator: 245x75x135mm (10x3x5.3 inch)</p> <p>Additional accessories have the following dimensions:</p> <p>Charging Dock: 305 x 95 x 110 mm (12 x 3.8 x 4.4 inches)</p> <p>Battery Pack: 105 x 30 x 65 mm (4.2 x 1.2 x 2.6 inches)</p>	<p>Hand-held Microwave Generator: 245x75x135mm (10x3x5.3 inch)</p> <p>Additional accessories have the following dimensions:</p> <p>Charging Dock: 305 x 95 x 110 mm (12 x 3.8 x 4.4 inches)</p> <p>Battery Pack: 105 x 30 x 65 mm (4.2 x 1.2 x 2.6 inches)</p>	Identical
Weight	<p>Hand-held Microwave Generator: Less than 0.75kg (~1.65lbs)</p> <p>Additional accessories have the following weight:</p> <p>Charging Dock: Less than 0.8 kg (~1.75 lbs)</p>	<p>Hand-held Microwave Generator: Less than 0.75kg (~1.65lbs)</p> <p>Additional accessories have the following weight:</p> <p>Charging Dock: Less than 0.8 kg (~1.75 lbs)</p>	Identical

	Battery Pack: Less than 0.25 kg (~0.55 lbs)	Battery Pack: Less than 0.25 kg (~0.55 lbs)	
Material	<p><u>SwiftPro Enclosure Material</u> Hand-Held Microwave Generator: ABS/PC CYCOLOY™ Resin HC1204HF Tip material: ABS/PC CYCOLOY™ Resin HC1204HF Biobarrier material: SILPURAN® 6000/70 Liquid Silicone Rubber</p> <p>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.</p>	<p><u>SwiftPro Enclosure Material</u> Hand-Held Microwave Generator: ABS/PC CYCOLOY™ Resin HC1204HF Tip material: ABS/PC CYCOLOY™ Resin HC1204HF Biobarrier material: SILPURAN® 6000/70 Liquid Silicone Rubber</p> <p>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.</p>	Identical
Energy	Microwave Mains Power and/or Battery	Microwave Mains Power and/or Battery	Identical
Maximum Microwave Power	0-10 in 1power level increments = treatment, 6W = Generator Tip ATO2 restricts delivered energy to 6W output (corresponds to a power level setting on generator of 10)	0-10 in 1power level increments = treatment, 6W = Generator Tip ATO2 restricts delivered energy to 6W output (corresponds to a power level setting on generator of 10)	Identical
Isolation	BF	BF	Identical
Time settings	0-10 secs	0-10 secs	Identical
Tip usable lifetime	15 minutes	15 minutes	Identical
Coagulation cycle	10 seconds	10 seconds	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, low battery, battery error	Alerts: MSM overtemp, Expired tip, No applicator detected, Reflection, Manual Switch Status System error, SD Card Error, Service error, low battery, battery error	Identical
Software/ Firmware Platform	Yes	Yes	Identical
Hardware control	Yes	Yes	Identical
Monitored	Power,	Power,	Identical

parameters	Time, Reuse status, Applicator connected Reflected power Battery Charge	Time, Reuse status, Applicator connected Reflected power Battery Charge	
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	Identical
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 /1 Seconds AT02 6J delivered	10 J/mm2 Set power level 10 /1 Seconds AT02 6J delivered	Identical

Electrical 60601 & EMC Compliant	Yes	Yes	Identical
Biocompatible	Yes	Yes	Identical
Human Factors and Usability Engineering	The swiftPro Systems comply with the requirements of all applicable Human Factors and Usability standards.	The swiftPro Systems comply with the requirements of all applicable Human Factors and Usability standards.	Identical
Electrical Safety and EMC Testing	Electrical safety and EMC testing were conducted, and the swiftPro System complies with all applicable Medical electrical equipment standards for safety and essential performance	Electrical safety and EMC testing were conducted, and the swiftPro System complies with all applicable Medical electrical equipment standards for safety and essential performance	Identical

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

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

The Swift™ Applicator Tips (SWF-AT01) and The swiftPro™ Applicator tips SWF-AT02 & SWF-AT03 are the only components within the Swift™ and swiftPro™ Systems intended for patient contact, and they are identical to those used in the predicate device Swift (K181941) and swiftPro (K240518).

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted and the Swift™ and swiftPro™ Systems comply with all the applicable Medical electrical equipment standards for safety and essential performance including but not limited to:

- 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.

To ensure continued compliance with updated EMC standards, a minor modification was made to the Swift device (K181941) to incorporate a screened loom. As a result, electromagnetic compatibility (EMC) testing was repeated and updated. The revised EMC and electrical safety reports confirm that the Swift™ System remains in compliance with all applicable safety and regulatory requirements.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided in accordance with IEC 62304:2006 (AMD1: 2015) and FDA guidance for software contained in medical devices. There has been no significant changes to the application of software and firmware for the SwiftPro™ System (K240518).

The Swift System (K181941) does not have a software function.

Cybersecurity

The Swift™ and swiftPro™ Systems 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 Swift™ and swiftPro™ Systems do not incorporate an OTS operating system or OTS software/drivers which supports hard-wired or wireless network connections.

Human Factors and Usability Engineering

The Swift and swiftPro Systems 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

Non-clinical bench performance testing is not required to support this submission.

Clinical Study

Clinical testing of the Swift System included a pivotal study of 119 subjects. Substantial equivalence was on this pivotal study.

Pivotal Study (IDE G220047)

The pivotal study was a randomized, multi-site, open, parallel-group, controlled, blind assessed study to compare the Swift System to cryotherapy for the treatment of common and plantar warts. The study was conducted at 6 investigational sites in the US. A total of 119 subjects were randomized to generate an evaluable Per Protocol population of 93 subjects for the primary endpoint analysis. The 26 subjects excluded from the Per Protocol population comprised 23 subjects who withdrew before the 3-month primary endpoint visit (which included the wart resolution assessment), 2 subjects who missed the primary endpoint visit but participated in subsequent follow-up visits, and 1 subject who attended the primary endpoint visit without the wart resolution assessment being completed.

For the purposes of statistical analysis and patient recruitment, safety and efficacy in the following patient groups have not been established: mosaic and warts (common or plantar) that have been reported by the subject as present for more than 5 years.

Safety and efficacy in the following patient groups have not been established as they were excluded from the clinical trial: pregnant, breast feeding, unstable co-morbidities (cardiovascular disease, active malignancy, inflammatory arthritis), peripheral neuropathy, immunosuppression disorders through illness or medication, autoimmune disease, diabetes (Type I or II), a history of infection in designated treatment area within 90 days, peripheral vascular disease, peripheral ischemia, vasculitis, Raynaud's, dependent lymphedema, congestive heart failure, history of repeated cellulitis, history of deep venous thrombosis, prior dissection of axillary lymph nodes (for treated hand) or inguinal lymph nodes (for treated feet), receiving prescribed blood thinning medication, vascular interventions to the legs deemed as an unacceptable risk, in receipt of any topical metallic treatment (e.g, aluminum chloride, silver nitrate) within the past year and those with an Implantable Cardioverter Defibrillator (ICD) or intolerance to microwave therapy.

Safety and efficacy in the following treatment areas have not been established as they were excluded from the clinical trial: thin or sensitive skin e.g., face, neck, armpits, breasts, buttocks or genitals; irritated, reddened or showing any sign of inflammation; metal implants at site of treatment; warts for treatment with hair growth, birthmarks, dark moles, pigmented skin or any other unusual skin condition

There were 61 subjects randomized to the Swift System treatment group and 58 subjects randomized to the cryotherapy group. In the Per Protocol population, there were 49 subjects in the Swift System treatment group and 44 subjects in the cryotherapy group. The overall mean age of subjects was 38.7 years, with 59 male subjects and 60 female subjects treated. The study population included White (87%), Black or African American (8%), Asian (4%) and American Indian or Alaskan Native (1%) subjects. Approximately 49% subjects presented with common warts for treatment and 51% of subjects with plantar warts.

Study Objectives

The objectives of the study were to collect definitive evidence of the safety and effectiveness of the Swift system for the specified intended use of microwave treatment of common and plantar warts and compare with cryotherapy.

Primary Effectiveness Endpoint

Clearance of all treated warts, each of which is defined as "resolved" or "not resolved" based on the classification by the blinded site investigator assessing the treated warts at three months post final treatment (up to 5 warts in total per subject).

Resolution of each treated wart was defined as

- i. lesion no longer visible, and
- ii. return of dermatoglyphics to the affected area, and
- iii. no pain on lateral compression.

Effectiveness Results

In the Per Protocol population where all subjects had a 3-month resolution assessment conducted (93 evaluable subjects), the percentage results show a nonsignificant difference between the two treatment groups (38.8% Swift System vs 38.6% Cryotherapy). The analysis showed that the primary endpoint for non-inferiority was inconclusive ($p=0.158$).

The effectiveness results at the three-month visit were calculated using data from 93 subjects. A total of 26 subjects were excluded from this analysis due to missing data. From a statistical perspective, the performance between the Swift System and Cryotherapy is not masked by missing data. Due to the higher than expected subject drop-out rate (target was 98 evaluable subjects), there is insufficient data to conclude that the Swift System is non-inferior (or superior) to Cryotherapy.

The pivotal study did not meet its primary endpoint for non-inferior effectiveness. From a clinical perspective, it appears the response rates were nearly identical.

There was a difference in efficacy for the Swift System treatment group in the clearance of plantar warts between the treatment groups in the Per Protocol population (48.0% in the Swift System group vs. 36.4% in the Cryotherapy group). The Swift System treatment showed a per patient 56% average reduction in any wart type size, compared with Cryotherapy, which had a 44% reduction.

Safety

The safety results show a reasonable assurance of safety for the Swift System, indicating that the Swift System may be used safely for the treatment of common and plantar warts:

- No serious adverse events were reported related to the device and no other safety concerns were identified during the study.
- A significantly larger proportion of the Swift System treatment group subjects (18%, n=11/61) reported zero adverse events as compared to the Cryotherapy group (3%, n=2/58).
- Overall safety:
 - The Swift System treatment group had fewer reported adverse events overall, approximately (40%) compared to Cryotherapy treatment group (60%).
- A lower number of specific adverse events were reported in the Swift System treatment group than the Cryotherapy group:
 - Medical device site pain: 35% (Swift System) vs. 65% (Cryotherapy)
 - Application site vesicles (blistering at treatment site): 30% (Swift System) vs. 70%(Cryotherapy)
 - Application site pruritus: 33% (Swift System) vs. 67% (Cryotherapy)
 - Medical device site paraesthesia: 35% (Swift System) vs. 65% (Cryotherapy)
 - Application site discolouration: 43% (Swift System) vs. 57% (Cryotherapy)
 - Medical device site hypersensitivity: 38% (Swift System) vs. 62% (Cryotherapy)

Post Treatment Pain

The Swift System treatment consistently resulted in less pain 10 minutes after treatment compared to Cryotherapy across all treatment sessions. A higher percentage of subjects in the Swift System treatment group reported no pain, with 90% after the first treatment, compared to 62% for Cryotherapy. This trend continued through subsequent treatments, with fewer subjects in the Swift System treatment group reporting mild pain overall.

VIII. CONCLUSIONS

The Swift™ and swiftPro™ Systems have the same intended use, technological characteristics and principles of operation with an addition of a specific common and plantar warts indications for use as compared to the predicate devices Swift™ (K181941) and swiftPro (K240518). Performance data including clinical study data has demonstrated a reasonable assurance of safety and effectiveness for the addition of treatment of common warts and plantar warts to the indications for use. A clinical study of the Swift™ System has demonstrated safety and effectiveness profiles of the device. The subject device (Swift™ and swiftPro™ Systems) are substantially equivalent to and as safe and effective as the predicate devices as indicated for use.