October 18, 2018

Emblation Ltd
Mairi Macfadyen
Director of Regulatory & Quality
Forrester Lodge, Inglewood
Alloa, FK10 2HU United Kingom

Re: K181941
Trade/Device Name: Swift System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: July 13, 2018
Received: July 20, 2018

Dear Mairi Macfadyen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA

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for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181941

Device Name
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 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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510K Summary

I. SUBMITTER

Emblation Limited
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Contact Person: Mairi MacFadyen
Director of Regulatory and Quality

Date Prepared: October 17, 2018

II. DEVICE

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 DEVICE

Trade Name: Microwave Tissue Coagulation System (MTCS)
Common Name: Microwave ablation system and accessories
510K Number: K072870
Manufacturer: Foundry Newco X, Inc

Trade Name: DTS G2 System
Common Name: Microwave ablation system and accessories
510K Number: K082819
Manufacturer: Miramar Lab, Inc

Trade Name: Emprint Ablation System
Common Name: Microwave ablation system and accessories
510K Number: K133821
Manufacturer: Covidien LLC

Reference Device

Trade Name: Miradry System MD4000
Common Name: Microwave ablation system and accessories
510K Number: K180396
Manufacturer: Miramar Lab, Inc

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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 consists of a compact, lightweight power generator with a software free controlled interface, cable and applicator with a single use disposable tip. The generator is intended to generate microwave energy at a frequency of 8GHz, maximum output power of 20Watts, and the distal end of the applicator radiates the microwave energy to effect thermal heating in the tissue. A typical surface area would be around 5mm diameter but would depend on the power & time selected.

The Swift® System interface is extremely intuitive with only two dials requiring to be set which are; output power (watts) & treatment duration (seconds). The applicator/cable connection and the generator/cable connection have been designed to only be connected in a certain way with a single, simple connection mechanism. This prevents the possibility of system malfunction due to incorrect setup or confusion. While the Swift® applicator tip has been designed to prevent re-use and hence mitigate the possibility of cross-contamination should the device not been changed from patient to patient.

The Swift® System comprises of the following components:

- Swift® Generator
- Swift® Applicator handpiece
- Swift® Applicator tip
- Swift® Interconnect Cable
- Swift® Footswitch (optional).

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 cardiac procedures.

Both the Swift® System and predicate devices have the same intended use for the coagulation of soft tissue. The Indications for Use statement for the Swift® System is not identical to the predicate devices; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Microwave coagulation is the technological principle for both the Swift® System and predicate devices. 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 the size of the target area.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Applicator/antenna – used to treat the target tissue
  - The subject and predicate devices share equivalent microwave feed network, coaxial connectors, cabling and materials (Emprint)
  - The subject and predicate devices share similar system architecture, medical PSU family/vendor, power regulation scheme, applicator identity technique (Emprint)
  - The subject and predicate devices share similar hardware architecture, materials, caseworks (Emprint)
  - The subject and predicate devices share similar radiating antenna method, ceramic dielectric waveguide (MTCS, DTS)
  - The subject and predicate devices share similar applicator architecture, (MTCS, DTS)
- User – controlled
  - The subject and predicate devices share similar control interfaces and similar alert features (Emprint)
- Software free
  - The subject and predicate devices share similar software free, hardware logic based control systems (Emprint)

The following technological differences exist between the Swift® System and predicate devices:

- Microwave frequency - the subject and predicate devices differ in that the Swift® System operates at 8 GHz , the subject and predicate devices differ in that the MTCS/DTS treatment system operates at 2.45 GHz/ 5.8 GHz, the subject and predicate devices differ in that the Emprint operates at 2.45 GHz
- Cooling
  - The Swift® System and predicate devices differ in that the Swift® System does not require cooling to apply a surface contact low power (10W) ablation.
  - The subject and predicate devices differ in that the MTCS/DTS requires cooling to apply a surface contact sub-dermal higher power treatment. (60W)
  - The subject and predicate devices differ in that the Emprint system requires cooling to deliver 100W via miniature coaxial structures for interstitial and percutaneous application

- Sterile
    - The Swift® applicator tip is provided as non-sterile and deemed equivalent in use to that of reference device, miraDry System MD4000, K180396. miraDry is a derivative of DTS G2 but includes a non-sterile bioTip.
    - The Swift® applicator tip and predicate devices differ in that the predicates are sterilised for interoperative and percutaneous applications.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination, using the same methods used for the predicate devices.

The biocompatibility evaluation was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The following tests were performed:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Hemolysis

Electrical safety and EMC testing were conducted and the Swift® System complies with all applicable Medical electrical equipment standards for safety and essential performance as follows;

Ex vivo and In Vivo testing

In the animal study conducted, 4 pigs underwent 11 treatments. There were no procedure related complications or premature deaths in this study. The safety and feasibility of the Swift® System were evaluated by macroscopic and histological evaluation of the treated tissue. The studies demonstrated that the Swift® System can safely create a thermal ablation similar to that which is constructed using other microwave devices.

In the in-vivo comparison studies between the subject Swift® System and the comparative predicate datasets from MTCS, DTS-LT, Accu20s, and Emprint, the Swift® System demonstrated a comparable trend in performance between the subject and the elected predicate example data. In terms of energy density this has been added to performance comparison relating to the predicate examples.

With reference to the IFU data for the MTCS and DTS-LT predicate systems the mean and range of energy densities (J/mm² and J/mm³) was compared with the ex-vivo test data across porcine muscle, liver and kidney tissues measured with the Swift® System. The Swift® System is able to deliver a marginally lower average area energy density in J/mm² than both the

MTCS and DTS-LT systems; it also achieves a maximum area energy density less than both systems.

This suggests that the treatment performance of Swift® System in terms of average area energy density due to the utilisation of a higher frequency (8GHz) but lower power was comparable in terms of performance to that of the un-cooled MTCS which reported equivalent average energy densities.

The Swift® System also recorded lower average volumetric energy density that the cooled DTS-LT which reported higher energy densities possibly due to the impact of cooling reducing the effective ablation zone.

VIII. CONCLUSIONS

No new characteristics have been determined that could impact performance, safety or effectiveness compared to the predicate examples and it can be concluded that the Swift® System is equivalent in terms to the nominated predicate devices.