July 9, 2020

Galil Medical Inc.
Amy McKinney
Sr. Regulatory Affairs Manager
4364 Round Lake Road
Arden Hills, Minnesota 55112

Re: K200061
Trade/Device Name: HEATfx Microwave Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: June 2, 2020
Received: June 3, 2020

Dear Amy McKinney:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K200061

Device Name
HEATfx Microwave Ablation System

Indications for Use *(Describe)*
The HEATfx Microwave Ablation System and Accessories are intended for the ablation (coagulation) of soft tissue in percutaneous, open surgical, and laparoscopic surgical settings.
The HEATfx Microwave Ablation System is not intended for use in cardiac procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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K200061
510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter:	Galil Medical Inc. 4364 Round Lake Road Arden Hills, MN 55112
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Device Name:	HEATfx Microwave Ablation System
Device Classification Name:	System, ablation, microwave and accessories
Regulation Number:	21 CFR 878.4400
Product Code:	NEY
Predicate Devices:	Emprint Ablation System (K133821) Emprint Ablation System (K163105)
Reference Devices:	Multi-Point Thermal Sensor (K060390)
Date of Preparation:	July 7, 2020

Device Description:

The HEATfx Microwave Ablation System is a mobile system intended to deliver microwave energy for thermal tissue ablation using a minimally invasive procedure. The HEATfx Microwave Ablation System is comprised of a console with optional cart, microwave ablation needles with cooling water manifold, optional thermal sensor, and related accessories.

The HEATfx console is computer-controlled with a touch screen user interface that allows the user to control and monitor the procedure. The HEATfx System utilizes three 2450 MHz, 145W generators to deliver microwave energy to up to three HEATfx Needles.

The HEATfx Microwave Ablation Needles are inserted into the target lesion under ultrasound or CT image guidance during laparoscopic procedures, or using direct visualization during surgical procedures, and operated using the console. The needles incorporate an antenna that transmits the microwave energy uniformly around the needle shaft. When connected to the HEATfx console, the console's internal pump and a disposable water manifold circulate sterile water through the needle for needle cooling and facilitating a uniform ablation zone.

The optional Multi-Point Thermal Sensor allows the user to monitor tissue temperatures near critical structures during an ablation procedure.

The system must be used with an irrigation bag of sterile water (not provided with the system).

Indications for Use / Intended Use:
The HEATfx Microwave Ablation System is indicated for use in the ablation (coagulation) of soft tissue in percutaneous, open surgical, and laparoscopic surgical settings.

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

Technological Characteristics:
The HEATfx Microwave Ablation System operates at 2.45 MHz and can deliver up to 145 W of microwave energy on up to 3 channels. The user has the ability to set desired power and time limits based on the desired ablation zone for the target tissue using the ablation zone model data presented in the Instructions for Use. The table below provides a summary of the technological characteristics of the HEATfx Microwave Ablation System as compared with the predicate device.

Optional accessories available for use with the HEATfx System include a cart and a Multi-Point Thermal Sensor. The HEATfx Needles are packaged with Cable Clips, Cable Adhesives, and an Adjustable Depth Guide, for optional use.

Feature / Specification	HEATfx Microwave Ablation System (K200061)	Emprint Ablation System (K133821 and K163105)	Comments / Rationale
Indications	The HEATfx Microwave Ablation System is indicated for use in the ablation (coagulation) of soft tissue in percutaneous, open surgical, and laparoscopic surgical settings. The HEATfx Microwave Ablation System is not intended for use in cardiac procedures.	The Covidien Emprint Ablation System is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of nonresectable liver tumors. The Covidien Emprint Ablation System is not intended for use in cardiac procedures.	Substantially equivalent; The HEATfx System indications are a subset of the predicate device indications.
Principles of Operation	User-controlled microwave energy delivery to tissue and needle cooling mechanism	User-controlled microwave energy delivery to tissue and needle cooling mechanism	Same as predicate
Generator Frequency	2.45GHz +/- 50 MHz	2.45GHz +/- 50 MHz	Same as predicate
System Output Power Range	Up to 145 Watt per channel	Up to 100 watts	Substantially equivalent; The differences were verified not to be clinically significant.
Console General Features	Software controlled generator with touchscreen interface; Integrated peristaltic pump for water cooling; Automatic pump start/stop; 3 Channels	Generator with analog and digital circuits; no software or firmware; Separate peristaltic pump for saline cooling; Manual pump start/stop; 1 Channel	Substantially equivalent; The difference in features is directly related to HEATfx proprietary software incorporating automated controls and multiple channel capability.
Temperature Monitoring Capability	Up to 2 Multi-Point Thermal Sensors for a total of 8 external temperature measurements	Single temperature sensor for 1 external temperature measurement	Substantially equivalent; The HEATfx System provides the user with

Feature / Specification	HEATfx Microwave Ablation System (K200061)	Emprint Ablation System (K133821 and K163105)	Comments / Rationale
			greater flexibility and procedure information.
Cooling Circuit and Fluid	Yes; sterile water	Yes; saline	Substantially equivalent; The difference in fluid option between HEATfx and the predicate does not present any adverse clinical consequences for the patient.
Needle Shaft Length	15, 20 cm	15, 20, 30 cm	Substantially equivalent; Galil has elected not to provide a longer length needle shaft.
Needle Shaft Outer Diameter	14 G (2.1 mm)	13 G (2.4 mm)	Substantially equivalent; The diameters of the needle shafts are comparable.

Summary of Performance Data and Substantial Equivalence:
A full battery of verification and validation testing was conducted on the HEATfx Microwave Ablation System to ensure that the design, functionality, and performance met all the specified requirements and that the features of the system satisfy its intended use. Testing was conducted according to protocols based on international standards and in-house requirements. The table below summarizes the verification and validation testing conducted on the HEATfx System.

Type of Testing	Objective
System Testing	Verified functional requirements of the complete system
Mechanical Testing	Verified the mechanical robustness of the console, including functional testing of cooling circuit, dimensional verification, mechanical safety testing, and packaging and labelling testing
Electrical Testing	Verified ability of the system to drive the pump and apply microwave power to the antenna and verified electrical safety and electromagnetic compatibility and immunity in accordance with IEC 60601-2-6 and FDA-recognized versions of IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2
Software Testing	Verified functionality of units of software and of the entire software package in accordance with FDA-recognized IEC 62304 standard and FDA Guidance documents "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (2005) and "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (2014)*
Needle Testing	Verified safety and functionality of the HEATfx Needles
Multi-Point Thermal	Verified the requirements and functionality of Multi-Point

Type of Testing	Objective
Sensor Testing	Thermal Sensor to monitor ablation temperatures
Ex-Vivo Testing	Verified and validated ablation zone dimensions and comparability to the predicate
In-Vivo Testing	Validated the use of the HEATfx system and workflow in an in-vivo model and realistic operating room environment
Biocompatibility Testing	Verified biocompatibility of materials per applicable ISO 10993 standards
Usability Testing	Verified usability of the system in compliance with applicable FDA-recognized versions of AAMI / ANSI / IEC 62366 and AAMI / ANSI HE75 standards, as well as FDA Guidance "*Applying Human Factors and Usability Engineering to Medical Devices*" (2016)
Packaging Testing	Validated performance and stability of the HEATfx Needle packaging in accordance with FDA-recognized versions of ISO 11607-1 and ISO 11607-2 standards
Sterility Testing	Validated sterilization parameters to ensure the sterility of the HEATfx Needles in accordance with FDA-recognized versions of ISO 11737-1, ISO 11737-2, and ISO 11135 standards
Pyrogenicity Testing	Verified that the HEATfx Needles do not produce material-mediated pyrogenicity

The software/firmware for HEATfx Microwave Ablation System was developed to maintain medical device functionality and safety by considering the cybersecurity framework core functions as outlined in FDA's Guidance document titled "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.*" Cybersecurity vulnerabilities were identified, and controls were implemented to mitigate the risks and vulnerabilities. Cybersecurity will continue to be monitored throughout the lifecycle of the HEATfx System.

Test results demonstrated that the HEATfx Microwave Ablation System meets defined specifications, is substantially equivalent to the predicate device, and does not raise any new issues of safety and effectiveness for its intended use.

The HEATfx Microwave Ablation System was shown to be similar in technology, indications for use, materials, and performance as the predicate devices. Differences between the two devices were verified via comparison testing not to be clinically significant. The HEATfx System is substantially equivalent to the Emprint System.

Conclusion:
The information and data provided in this Traditional 510(k) Premarket Notification establish that the HEATfx Microwave Ablation System is substantially equivalent to the legally marketed predicate device with regard to performance, safety, and effectiveness for its intended use.