May 15, 2018

Galil Medical Inc.
Ms. Rachel Owens
Sr. Regulatory Affairs Specialist
4364 Round Lake Road
Arden Hills, Minnesota 55112

Re: K181153
Trade/Device Name: ICEfx Cryoablation System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: April 30, 2018
Received: May 1, 2018

Dear Ms. Owens:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Jennifer R. Stevenson -S3

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)*
K181153

Device Name
ICEfx™ Cryoablation System

Indications for Use *(Describe)*
The ICEfx Cryoablation System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology and urology. This System is designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, skin lesions) by the application of extremely cold temperatures.

The ICEfx Cryoablation System has the following specific indications:

- Urology Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH)
- Oncology Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention
- Dermatology Ablation or freezing of skin cancers and other cutaneous disorders; Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin
- Gynecology Ablation of malignant neoplasia or benign dysplasia of the female genitalia
- General surgery Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas
- ENT Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth
- Thoracic surgery (with the exception of cardiac tissue)
- Proctology Ablation of benign or malignant growths of the anus or rectum

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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K181153
510(k) SUMMARY
ICEfx™ Cryoablation System
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:	ICEfx™ Cryoablation System
Device Classification Name:	Cryosurgical unit and accessories
Regulation Number:	21 CFR 878.4350
Product Code:	GEH
Predicate Device 510(k):	Visual-ICE Cryoablation System (K113860)
Date of Preparation:	April 30, 2018

Device Description:
The ICEfx™ Cryoablation System is a mobile system intended for cryoablative tissue destruction using a minimally invasive procedure. The system is computer-controlled with a touch screen user interface that allows the user to control and monitor the procedure. The therapy delivered by the system is based on the Joule-Thomson effect displayed by compressed gases. The ICEfx System uses high-pressure argon gas that circulates through closed-tip cryoablation needles to induce tissue freezing. Active tissue thawing is achieved by the use of Galil Medical CX technology in which a heating element inside the cryoablation needle can be energized to cause thawing.

The table below provides a summary comparison of the submitted device compared to the predicate device.

Description of Submitted Device: ICEfx Cryoablation System	**Comments related to Predicate:** Visual-ICE Cryoablation System (K113860)
Design and Construction	
Console	Similar to predicate; ICEfx is smaller and lighter weight
Needle ports	ICEfx contains fewer needle ports
Channel Lock	Same as predicate

Description of Submitted Device: ICEfx Cryoablation System	**Comments related to Predicate:** Visual-ICE Cryoablation System (K113860)
User interface	Similar to predicate; touchscreen with equivalent function and features
Needle Interface	Same as predicate
Performance and Function	
Principles of Operation: Freezing / Thawing	Same as predicate; ICEfx does not support the option for helium thaw
CX Technology for Electrical Thawing	Same as predicate
Needle Compatibility	Same as predicate; ICEfx supports fewer needles

In summary, the submitted ICEfx Cryoablation System has the same technology and principle of operation as the predicate device.

Indications for Use / Intended Use:
The ICEfx Cryoablation System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology and urology. This System is designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, skin lesions) by the application of extremely cold temperatures.

The ICEfx Cryoablation System has the following specific indications:
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- Thoracic surgery (with the exception of cardiac tissue)
- Proctology Ablation of benign or malignant growths of the anus or rectum

The intended use and indications for use are the identical to the Visual-ICE predicate.

Summary of Performance Data and Substantial Equivalence:
A full battery of verification and validation testing was conducted on the ICEfx Cryoablation 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. Verification testing included system testing, electrical testing, mechanical

testing, labeling testing, and software testing. System testing assessed whether the functional requirements of the system as a whole were satisfied by the design. Mechanical testing evaluated the mechanical robustness of the system and sub-systems, functional testing of the gas system, and tests of mechanical safety requirements. Electrical testing assessed the functional aspects of the circuit assemblies, tests of electromagnetic compatibility and immunity (EMC/EMI), and tests of electrical safety requirements. Labeling verification evaluated user manual and labeling accuracy with respect to design requirements and risk mitigations. Software testing exercised individual units of software as well as tests of the functionality of the entire software package. Validation testing included design and usability testing. Test results demonstrated that the ICEfx Cryoablation 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.

Conclusion (Statement of Equivalence):
As the indications for use and fundamental scientific technology have not changed, the non-clinical performance data provided in this Special 510(k) Premarket Notification supports a determination that the ICEfx Cryoablation System is substantially equivalent to the legally marketed predicate device, with regard to performance, safety, and effectiveness for its intended use.