November 2, 2020

Galil Medical Inc.
Ms. Amy McKinney, MS, RAC
Sr. Regulatory Affairs Manager
4634 Round Lake Rd. W
Arden Hills, Minnesota 55112

Re: K203032
Trade/Device Name: IcePearl 2.1 CX 90 Needle, IcePearl 2.1 CX L 90 Needle, IcePearl 2.1 CX Needle, IceFORCE 2.1 CX 90 Needle, IceFORCE 2.1 CX L 90 Needle, and IceFORCE 2.1 CX Needle

Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: October 2, 2020
Received: October 5, 2020

Dear Ms. 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)*
K203032

Device Name
IcePearl 2.1 CX 90° Needle (FPRPR3601);IcePearl 2.1 CX L 90° Needle (FPRPR3617);
IcePearl 2.1 CX Needle (FPRPR3603);IceFORCE 2.1 CX 90° Needle (FPRPR3602);
IceFORCE 2.1 CX L 90° Needle (FPRPR3618);IceFORCE 2.1 CX Needle (FPRPR3604)

Indications for Use *(Describe)*

Galil Medical's IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needle families are intended for cryoablative destruction of tissue during surgical procedures. The IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needle families are 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. The systems are designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The Galil Medical IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needle families have 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 hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal 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, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenoma)
- 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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K203032
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 Ltd. Tavor Building 1 Industrial Park, PO Box 224 Yokneam Industrial Park 2069203 Israel
Company Contact Person:	Ms. Amy E McKinney, MS, RAC Sr. Manager, Regulatory Affairs Boston Scientific Corp
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Device Name:	IcePearl 2.1 CX Cryoablation Needle IceFORCE 2.1 CX Cryoablation Needle IcePearl 2.1 CX L Cryoablation Needle IceFORCE 2.1 CX L Cryoablation Needle
Device Classification Name:	Cryosurgical unit and accessories (GEH) 21 CFR 878.4350
Predicate Devices / Reference 510(k):	IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles (K152133) IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles (K162599)
Date of Preparation:	October 23, 2020

Device Description:

Galil Medical's IcePearl 2.1 CX, IceFORCE 2.1 CX, IcePearl 2.1 CX L, and IceFORCE 2.1 CX L Cryoablation Needles (collectively referred to as the 2.1 CX Cryoablation Needles) are sterile, single use, disposable components, when used in conjunction with Galil Medical's commercially available cryoablation systems, to perform cryoablative destruction of tissue. The needles are intended to convert high-pressure gas to either a very cold freezing application or to a warm thawing application.

The 2.1 CX Cryoablation Needles are disposable 2.1 mm needles that have a sharp cutting tip, a color-coded handle, a gas tube, and a connector. Both the IcePearl and IceFORCE needle families offer handles configured as straight and in a 90-degree angled configuration (to aid positioning of the needle within the CT imaging system gantry). Additionally, both needle families offer a long version of the needle that contains a longer needle shaft and a 90-degree angled handle configuration (IcePearl 2.1 CX L and IceFORCE 2.1 CX L).

The change presented in this Special 510(k) is an internal component change. There are no changes to the intended use, indications for use, or technological characteristics.

Intended Use:
There are no changes to the indications for use of the 2.1 CX Cryoablation Needles as a result of the component change in this 510(k).

Galil Medical's IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needle families are intended for cryoablative destruction of tissue during surgical procedures. The IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needle families are 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. The systems are designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The Galil Medical IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needle families have 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 hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal 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, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenoma)
• 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)

Technological Comparison:
The table below provides a summary comparison of the submitted devices compared to the predicate devices.

Description of Submitted Device:	Comments related to Predicates:
Design and Construction	
Needle Tip	Same as predicate
Needle Shaft	Shaft length is 55 mm longer than predicate
Gas Pathway Tubing	Same as predicate
Handle	Same as predicate
Needle Connector	Same as predicate
Internal heater assembly design	Same design as predicate; modified dimensions and modified material
Performance and Function	
Freezing/Thawing Technology	Same as predicate
Function	Same as predicate
Freezing Parameters	Same as predicate
Thaw Parameters	Same as predicate
Track Ablation	Same as predicate
Indications for Use	Same as predicate

The component change submitted in this Special 510(k) does not alter the technological characteristics of the IceFORCE and IcePearl 2.1 CX needle families. In summary, the modified IcePearl and IceFORCE needles submitted in this 510(k) have the same technology, same principle of operation, and same indications for use as the predicate devices.

Summary of Performance Data and Substantial Equivalence:
Verification and performance testing was conducted on needles built with the modified component to verify safety and performance characteristics and to establish substantial equivalence to the predicate devices.

This testing included:

- Thermal testing to ensure needle temperatures met specifications for freezing and thawing
- Electrical testing to verify electrical insulation of the needles
- Durability testing to verify durability of the modified component
- Freezing performance testing to verify that the needles meet freezing performance specifications.

Testing was done to established test methods documented in the original 510(k)s of the predicate devices. Test results demonstrated that the modified 2.1 CX Needles meet defined specifications, demonstrate improved reliability over the predicate devices, and do not raise any new safety or effectiveness issues.

Conclusion:
The information and data provided in this Special 510(k) Notification establish that the modified 2.1 CX Cryoablation Needles are substantially equivalent to the legally marketed predicate devices.