Ms. DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 11, 2016

Galil Medical Ltd.
Ms. Lynne Davies
Sr. Manager, Regulatory Affairs
4364 Round Lake Road
Arden Hills, Minnesota 55112

Re: K162599
Trade/Device Name: IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 15, 2016
Received: September 19, 2016

Dear Ms. Davies:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162599

Device Name
IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles

Indications for Use *(Describe)*
Galil Medical's IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles are intended for cryoablative destruction of tissue during surgical procedures. The IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles 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 L and IceFORCE 2.1 CX L Cryoablation Needles 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, and hemorrhoids)

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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K162599
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. Lynne A Davies Sr. Manager, Regulatory Affairs Galil Medical Ltd. Phone: 651-287-5098 Fax: 651-287-5099 Email: lynne.davies@btgplc.com
Alternate Contact Person:	Ms. Amy E McKinney VP, Regulatory Affairs and Quality Galil Medical Ltd. Phone: 651-287-5096 Fax: 651-287-5097 Email: amy.mckinney@btgplc.com
Device Name:	IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles
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)
Date of Preparation:	September 15, 2016

Device Description:
Galil Medical's IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles are sterile, single use, disposable components, when used in conjunction with Galil Medical's Visual-ICE Cryoablation System 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 IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles are disposable 2.1 mm needles that have a sharp cutting tip, a color-coded handle, a gas tube, and a connector. The IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles offer handles configured in a 90° angled configuration.

The IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles were designed to provide the same cryoablation functionality with the same iceball shapes as compared to Galil Medical's predicate needles, IcePearl 2.1 CX and IceFORCE 2.1 CX (K152133).

The new devices differ from the predicate devices in that the needle shaft is 55 mm longer than the needle shaft of the predicate devices. The longer shaft length was incorporated into the needles to treat deep-seated tumors in patients with a larger body habitus, while still allowing for CT gantry clearance using a 2.1 CX type needle. Galil Medical is using the alpha letter "L" identifier as part of the needle name as well as a different needle part numbers to assist users in distinguishing the different shaft length from the predicate devices.

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

Description of Submitted Device: IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles	**Comments related to Predicates:** IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles (K152133)
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
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

In summary, the submitted IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles have the same technology, principle of operation and indications for use as the predicate devices.

There are *no changes* to the Visual-ICE System Software. The previously cleared software is applicable for use with submitted IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles.

Intended Use:
Galil Medical's IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles are intended for cryoablative destruction of tissue during surgical procedures. The IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles 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 L and IceFORCE 2.1 CX L Cryoablation Needles have the following specific indications:

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- 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, and hemorrhoids)

Summary of Performance Data and Substantial Equivalence:
The IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles use the same technology and have the same intended use and method of operation as compared to the predicate devices.

Performance testing was conducted on the IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles with the previously cleared Visual-ICE System Software to verify safety and performance characteristics and to establish substantial equivalence. Testing was conducted according to protocols based on international standards and in-house requirements and included freezing and *in vivo* performance. Test results demonstrated that the IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles meet defined specifications 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 IcePearl 2.1 CX L and IceFORCE 2.1 CX L Cryoablation Needles are substantially equivalent to the legally marketed predicate devices.