July 30, 2018

Galil Medical Ltd.
% Ms. Stacey Bucklund
Director, Regulatory Affairs
BTG International Inc.
4364 Round Lake Road
Arden Hills, Minnesota 55112

Re: K181741
Trade/Device Name: IceSphere 1.5 CX Cryoablation Needle
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 28, 2018
Received: July 2, 2018

Dear Ms. Bucklund:

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,

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)*
K181741

Device Name
IceSphere™ 1.5 CX Cryoablation Needle

Indications for Use *(Describe)*
The Galil Medical 1.5 CX Cryoablation Needles are intended for cryoablative destruction of tissue during surgical procedures. The 1.5 CX Cryoablation Needles, when used with a Galil Medical Cryoablation System, are designed to destroy tissue by the application of extremely cold temperatures. A full list of specific indications can be found in the respective Galil Medical Cryoablation System User Manual.

For reference, the indications for use from the Galil Medical Cryoablation Systems User Manuals are provided below.

The Galil Medical Cryoablation Systems 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 (including prostate and kidney tissue, liver metastases, tumors, skin lesions) by the application of extremely cold temperatures. The Galil Medical Cryoablation Systems 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 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 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K181741

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 2069203 Israel
Company Contact Person:	Stacey Backlund Director, Regulatory Affairs BTG International Inc.
Phone:	267-414-3640
Fax:	610-943-6018
Email:	stacey.backlund@btgplc.com
Alternate Contact Person:	Rebeka Stoltman Director, Regulatory Affairs Galil Medical Inc.
Phone:	651-287-5020
Fax:	877-510-7757
Email:	Rebeka.stoltman@btgplc.com
Device Name:	IceSphere™ 1.5 CX Cryoablation Needle
Device Classification Name:	Cryosurgical unit and accessories
Regulation Number:	21 CFR 878.4350
Product Code:	GEH
Predicate Device 510(k):	IceSphere 1.5 90° Cryoablation Needle (K141485) IceRod 1.5 CX 90° Cryoablation Needle (K121251 & K140584)
Date of Preparation:	June 28, 2018

Device Description:

Galil Medical's IceSphere 1.5 CX Cryoablation Needle is a sterile, single use, disposable component, used in conjunction with a Galil Medical Cryoablation System to perform cryoablative destruction of tissue. The needle is intended to convert high-pressure gas to either a very cold freezing application or to a warm thawing application. Galil Medical's IceSphere 1.5 CX Cryoablation Needle is a disposable 1.5 mm needle that have a sharp cutting tip, a color-coded handle, a gas tube, and a connector. The IceSphere 1.5 CX Cryoablation Needle offers a handle configured in a 90° angled configuration (to aid positioning of the needle within the CT imaging system gantry).

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

Description of Submitted Device: IceSphere 1.5 CX Cryoablation Needle	**Comments Related to Predicates:** IceRod CX Cryoablation Needles (K121251 and K140584); IceSphere (K141485)
Design and Construction	
Needle Tip	Same as predicates
Needle Shaft	The active zone is the same length as IceSphere predicate device. The active zone length is shorter in comparison to the IceRod CX predicate resulting in markings and active zone indicator starting at a different point on the tip and a shorter non-stick coating length
Gas Pathway Tubing	Same as predicates
Handle	Same as predicate
Needle Connector	Same as predicates
Performance and Function	
Freezing/Thawing Technology	Same as predicates
Function	Same as predicates
Freezing Parameters	Same as predicate
Thaw Parameters	Same as predicates
Track Ablation	Functionally equivalent to IceRod CX predicate
Indications for Use	Same as predicates

In summary, the submitted IceSphere 1.5 CX Cryoablation Needle has the same technology and principle of operation as the predicate device.

Indications for Use / Intended Use:
The Galil Medical 1.5 CX Cryoablation Needles are intended for cryoablative destruction of tissue during surgical procedures. The 1.5 CX Cryoablation Needles, when used with a Galil Medical Cryoablation System, are designed to destroy tissue by the application of extremely cold temperatures. A full list of specific indications can be found in the respective Galil Medical Cryoablation System User Manual.

For reference, the indications for use from Galil Medical Cryoablation Systems User Manuals are provided below.

The Galil Medical Cryoablation Systems 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 (including prostate and kidney tissue, liver metastases, tumors, skin lesions) by the application of extremely cold temperatures. The Galil Medical Cryoablation Systems 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 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 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

The intended use and indications for use are the identical to the predicate needles.

Summary of Performance Data and Substantial Equivalence:
Verification testing was conducted on the IceSphere 1.5 CX Cryoablation Needle to ensure that the design, functionality, and performance met all the specified requirements and that the features of the needle satisfy its intended use. Testing was conducted according to protocols based on international standards and in-house requirements. Verification testing included functional testing, system compatibility testing, and labeling review. Functional testing assessed whether the electrical heater requirements and functional requirements were met. System compatibility testing ensured the needle would operate with a Galil Medical Cryoablation System. Labeling verification evaluated instructions for use and labeling accuracy with respect to design requirements and risk mitigations. Test results demonstrated that the IceSphere 1.5 CX Cryoablation Needle meets defined specifications, is substantially equivalent to the predicate devices, 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, verification testing provided in this Special 510(k) Premarket Notification supports a determination that the IceSphere 1.5 CX Cryoablation Needle is substantially equivalent to the legally marketed predicate devices, with regard to performance, safety, and effectiveness for its intended use.