



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

August 28, 2015

Galil Medical Ltd.  
% Ms. Lynne Davies  
Galil Medical Incorporated  
4364 Round Lake Road  
Arden Hills, Minnesota 55112

Re: K152133

Trade/Device Name: IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical unit and accessories  
Regulatory Class: Class II  
Product Code: GEH  
Dated: July 31, 2015  
Received: July 28, 2015

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" (21CFR 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,

**David Krause -S**

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

**Indications for Use Statement**

**510(k) Number (if known):**  K152133

**Device Name:** IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles

**Indications For Use:**

Galil Medical's IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles are intended for cryoablative destruction of tissue during surgical procedures. The IcePearl 2.1 CX and IceFORCE 2.1 CX 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 and IceFORCE 2.1 CX 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)

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

## Section 5. 510(k) Summary

### 510(k) SUMMARY

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

<b>Submitter:</b>	Galil Medical Ltd. Tavor 1 Building Shaar Yokneam Yokneam Industrial Park 20692 Israel
<b>Company Contact Person:</b>  Phone: Fax: Email:	Ms. Lynne A Davies Sr. Manager, Regulatory Affairs Galil Medical Ltd. 651-287-5098 651-287-5099 lynne.davies@galilmedical.com
<b>Alternate Contact Person:</b>  Phone: Fax: Email:	Ms. Amy E McKinney VP, Regulatory Affairs and Quality Galil Medical Ltd. 651-287-5096 651-287-5097 amy.mckinney@galilmedical.com
<b>Device Name:</b>	IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles
<b>Device Classification Name:</b>	Cryosurgical unit and accessories (GEH) 21 CFR 878.4350
<b>Predicate Devices / Reference 510(k):</b>	IceRod CX Cryoablation Needles (K121251 and K140584) IceEDGE 2.4 Cryoablation Needle (K111859) Visual-ICE Cryoablation System (K113860, K123865, K143564)
<b>Date of Preparation:</b>	July 28, 2015

#### Device Description:

Galil Medical's IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles are sterile, single use, disposable components, when used in conjunction with Galil Medical's Visual-ICE Cryoablation System Software Revision 1.4.0, 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 and IceFORCE 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 IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles offer handles configured as straight and in a 90° angled configuration (to aid positioning of the needle within the CT imaging system gantry).

The IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles were designed to provide the same cryoablation functionality with similar iceball shapes on a 2.1 mm shaft as compared to Galil Medical's predicate needles, IceRod CX (1.5 mm) needle and IceEDGE 2.4 mm needle.

The IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles differ from the predicate devices in that the reconfigured heat exchanger has been relocated from the needle shaft to the needle handle and an additional vacuum insulated tube has been incorporated into the handle. The changes were made to ensure optimal freezing performance utilizing a 2.1 mm shaft.

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

<b>Description of Submitted Device:</b> IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles	<b>Comments related to Predicates:</b> IceRod CX Cryoablation Needles (K121251, K140584); and IceEDGE 2.4 (K111859)
<b>Design and Construction</b>	
Needle Tip	Same as predicate
Needle Shaft	Shaft size (diameter) is in-between the shaft sizes of the predicates
Gas Pathway Tubing	Same as predicate
Handle	Same as the predicates with the exception of a larger diameter resulting from the incorporation of: <ul style="list-style-type: none"> <li>the reconfigured heat exchanger located in the proximal end of the handle toward the connector versus being in the needle shaft; and</li> <li>the addition of a vacuum insulation tube</li> </ul>
Needle Connector	Same as predicate
<b>Performance and Function</b>	
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 and IceFORCE 2.1 CX Cryoablation Needles have the same technology, principle of operation and indications for use as the predicate devices.

This Special 510(k) also contains changes to the Visual-ICE System software denoted as Software Release 1.4.0. Software Release 1.4.0 is an updated version of the Visual-ICE software previously cleared. There are no changes to the system hardware required as a result of the changes being made in the software. The following modifications were incorporated based on the added software support of the proposed IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles as well as customer and sales feedback to enhance the robustness of the software programming.

<b>User Interface Changes</b>	<ul style="list-style-type: none"> <li>Updated the needle selection dialog to display marketing names and to default to the currently selected needle type.</li> </ul>
<b>Service and</b>	<ul style="list-style-type: none"> <li>Added features for service personnel to diagnose and troubleshoot issues in the field.</li> </ul>

<b>Maintenance Changes</b>	These changes include: <ul style="list-style-type: none"> <li>○ Ability to access and troubleshoot to needle memory parameters from diagnostic screen</li> <li>○ Ability to export multiple log files to USB Stick</li> <li>● Modified the Visual ICE message to accommodate for 2 year service intervals.</li> </ul>
<b>Functional Changes</b>	<ul style="list-style-type: none"> <li>● Added support for needles that have been calibrated with heater wire temperature information during production. This allows for a lower needle shaft temperature display.</li> <li>● Added support for the 2.1 CX Cryoablation Needles to the software.</li> <li>● Added reporting of timeline when channel is disconnected.</li> <li>● Modified the software to display lowest temperature during freezing and to display temperatures in the MTS graphs without first having to test a needle.</li> </ul>
<b>User Interface and Functional Changes</b>	<ul style="list-style-type: none"> <li>● Added support and dialog messages related to real time feedback of power consumption by needles in i-Thaw, FastThaw, and cautery modes.</li> <li>● The big timers on the system are now easier to activate from different screens and display needle temperature.</li> <li>● Streamlined the channel controls by removing the redundant advanced features on the freeze and thaw dialogs.</li> <li>● Added the ability to FastThaw directly from the channel controls instead of having to filter through multiple menu options.</li> <li>● Added the ability to save and load multiple programmed cycles.</li> </ul>

**Intended Use:**

Galil Medical's IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles are intended for cryoablative destruction of tissue during surgical procedures. The IcePearl 2.1 CX and IceFORCE 2.1 CX 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 and IceFORCE 2.1 CX 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)

**Summary of Performance Data and Substantial Equivalence:**

The IcePearl 2.1 CX and IceFORCE 2.1 CX 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 and IceFORCE 2.1 CX Cryoablation Needles with Visual-ICE Software Revision 1.4.0 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 dimensional testing, functional testing, freezing performance, and *in vivo* needle track ablation, based on depth of tissue necrosis characterization. Test results demonstrated that the IcePearl 2.1 CX and IceFORCE 2.1 CX Cryoablation Needles when used with Visual-ICE Software Revision 1.4.0 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 and IceFORCE 2.1 CX Cryoablation Needles when used with Visual-ICE Software Revision 1.4.0 are substantially equivalent to the legally marketed predicate devices.