 AUG 28 2012

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.

Submitter:	Galil Medical Ltd. Tavor 1 Building Shaar Yokneam Yokneam Industrial Park 20692 Israel
Company Contact Person:	Ms. Lynne A Davies Sr. Regulatory Affairs Advisor Galil Medical Inc. Phone: 651-287-5098 Fax: 651-287-5099 Email: lynne.davies@galilmedical.com
Alternate Contact Person:	Ms. Amy E McKinney Director, Regulatory Affairs Galil Medical Inc. Phone: 651-287-5096 Fax: 651-287-5097 Email: amy.mckinney@galilmedical.com

Device Name:	IceRod CX Cryoablation Needle
Device Classification Name:	Cryosurgical unit and accessories (GEH) 21 CFR 878.4350
Predicate Devices / Referenced 510(k):	IceRod *PLUS* 17G Cryoablation Needles (K110946) IceRod i-Thaw 17G Cryoablation Needles (K060390)

Device Description:

The IceRod CX Cryoablation Needle is a sterile, single use, disposable component used in conjunction with Galil Medical's Visual-ICE Cryoablation System when performing cryoablative destruction of tissue. It is intended to convert high-pressure gas to either a very cold freezing application or to a warm thawing application. The IceRod CX disposable cryoablation needle has a 17G shaft, a sharp cutting tip, a color-coded handle, a gas tube, and a connector containing a small PCB board capable of relaying needle information such as needle type, lot number, and expiration date information to Galil's Visual-ICE Cryoablation System. Additionally, the needle exhibits markings to aid in positioning the needle in tissue. The IceRod CX needle differs from the predicate devices in that the distal shaft of the needle contains a non-stick coating and Galil's i-Thaw electrical thaw technology can be used for FastThaw and/or Track Ablation following a cryoablation procedure when used with Galil's Visual-ICE Cryoablation System.

Intended Use:
The Galil Medical IceRod CX Cryoablation Needle is intended for cryoablative destruction of tissue during surgical procedures. The IceRod CX Cryoablation Needle 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. 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 IceRod CX Cryoablation Needle 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 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 IceRod CX Cryoablation Needle uses the same technology and has the same intended use and method of operation as compared to the predicate devices. Both the new and predicate devices consist of a sharp cutting tip, a shaft, a color-coded handle, gas tubing, and a connector (with the exception of the PCB board). Both the new and predicate devices are comprised of similar materials (with the exception of the non-stick coating) and serve as conduits for high pressure gas during a cryoablation procedure.

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

Description of Submitted Device: **IceRod CX Cryoablation Needle**	**Comments related to Predicates:** IceRod *PLUS* 17G Cryoablation Needles (K110946) IceRod i-Thaw 17G Cryoablation Needles (K060390)
Design and Construction	
Needle Tip	Same as predicate
Needle Shaft	Same as predicate with the exception of the non-stick coating
Gas Pathway Tubing	Same as predicate
Handle	Same as predicate
Needle Connector	Same as predicate with the exception of the PCB board
Performance and Function	
Freezing/Thawing Technology	Same as predicate
Function	Same as predicate with the exception of the addition of the FastThaw and Track Ablation features.
Freezing Parameters	Same as predicate
Thaw Parameters	Same as predicate with the exception of the addition of the FastThaw feature
Track Ablation	New feature
Indications for Use	See below

Performance testing was conducted on IceRod CX Cryoablation Needle 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. Additionally, the needle meets the biocompatibility requirements outlined in ISO 10993. Test results demonstrated that the IceRod CX needle meets defined specifications and does not raise any new safety or effectiveness issues.

Conclusion:
The information and data provided in this 510(k) Notification establish that the IceRod CX Cryoablation Needle is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Galil Medical Limited
% Galil Medical Incorporation
Ms. Lynne A. Davies
Senior Regulatory Affairs Advisor
126 Mesquite Street
Lake Jackson, Texas 77566

AUG 28 2012

Re: K121251
Trade/Device Name: IceRod CX Cryoablation Needle
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: August 17, 2012
Received: August 20, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121251

Device Name: IceRod CX Cryoablation Needle

Indications For Use:
The Galil Medical IceRod CX Cryoablation Needle is intended for cryoablative destruction of tissue during surgical procedures. The IceRod CX Cryoablation Needle 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. 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.

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- Proctology (ablation of benign or malignant growths of the anus or rectum, and hemorrhoids)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121251