MAR 3 1 2014

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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 Sr Director, Global Regulatory Affairs and Quality 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 CX Cryoablation Needle (K121251)
Date of Preparation	March 6, 2014

Device Description:

Galil is requesting clearance of a laser marking process improvement technique used to create the "markings" on the needle shaft of the previously cleared IceRod CX Needle (K121251). Galil's IceRod CX Needle (K121251) is a sterile, single use, disposable component used in conjunction with Galil Medical's Visual-ICE Cryoablation System (K113860, K123865) when performing cryoablative destruction of tissue. The needle has a sharp cutting tip, a 1.5mm (17G) shaft, a color-coded handle, gas tubing, and a connector. The handle is in a 90° configuration to aid positioning of the needle within the CT imaging system gantry. The IceRod CX needle contains shaft markings to aid the physician in needle placement. There are no changes to the marking dimensions on the needle. Only the marking technique has been modified.

Since Galil is requesting clearance for a revised shaft marking process improvement technique for the IceRod CX Cryoablation Needle, the needle design itself (with the exception of the shaft marking method) has not changed. There are no other design, specification, process, or material changes to the needle; additionally, the model number of the needle is unchanged.

Table 1 provides a summary comparison of the changes related to the shaft marking process for Galil's IceRod CX.

Table 1 Summary of Changes

Description of Device	Comments related to the previously cleared IceRod CX (K121251)
Design and Construction	
Needle Tip	Same
Needle Shaft	Same
Needle Shaft Marks	Same
Needle Shaft Marking Material	Laser marking process replaces the Electro Etching process
Needle Shaft Marking Technique	Laser marking process replaces the Electro Etching process
Gas Pathway Tubing	Same
Handle	Same
Needle Connector	Same
Performance and Function	
Freezing/Thawing Technology	Same
Function	Same
Freezing Parameters	Same
Thaw Parameters	Same
Track Ablation	Same
Indications for Use	Same

Therefore as outlined in Table 1 the IceRod CX Needle, incorporating the revised shaft marking technique, has the same:

- device design;
- materials;
- principle of operation; and
- mechanism of action.

Intended Use:
There have been ***no changes*** to the Indications for Use Statement as a result of the modifications contained in this Special 510(k) from that cleared via Galil's IceRod CX K121251.

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 needle design, with the exception of the laser marking process improvement technique for the "markings" on the needle shaft, remains the same and therefore, the design verification testing located in Section 18 Performance Testing – Bench provided in K121251 is applicable. Therefore, since the shaft marking technology is the only change being made to Galil's IceRod CX needle, Galil Medical conducted shaft qualification testing, heat affected zone measurements and shaft marking quality and adherence to specifications. The tests were conducted to ensure the laser marking on the needle shaft does not impact the needle integrity and thereby verify safety and performance characteristics and to establish substantial equivalence.

Conclusion:
Galil Medical believes the information and data provided in this Special 510(k) Notification establishes that the IceRod CX Needle utilizing the laser marking process improvement technique to "mark" the needle shaft does not affect safety or effectiveness, or raise different questions of safety and effectiveness from that cleared in the original IceRod CX 510(k) K121251 and is therefore, substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 31, 2014

Galil Medical Ltd.
Ms. Lynne A. Davies
Senior Regulatory Affairs Advisor
4364 Round Lake Road
Arden Hills, Minnesota 55112

Re: K140584
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: March 6, 2014
Received: March 7, 2014

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 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. 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,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting 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): K140584

Device Name: IceRod CX Cryoablation Needle

Indications For Use:
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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)