GALILMEDICAL
Leading Through Innovation

JUL 0 2 2014

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 and Quality 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:	IceSphere Cryoablation Needle
Device Classification Name:	Cryosurgical unit and accessories (GEH) 21 CFR 878.4350
Predicate Devices / Referenced 510(k):	Cryoablation Probe (IceSphere Cyroablation Needle) Referenced Galil 510(k): K060390, K021261, K113860, K110946
Date of Preparation	June 4, 2014

Device Description:

Galil Medical's predicate IceSphere needles and Galil's proposed IceSphere needles are sterile, single use, disposable devices used in conjunction with Galil Medical's cleared cryoablation systems (SeedNet, SeedNet Gold; Presice; Visual-ICE) for cryoablative destruction of tissue during surgical procedures. The needles have a sharp cutting tip, a 1.5mm (17G) shaft, a color-coded handle, gas tubing, and a connector. Galil's predicate and proposed IceSphere needles are available in 2 handle configurations: straight and 90°. The needles contain shaft markings to aid the physician in needle placement.

Galil is requesting clearance of the proposed vacuum insulated IceSphere needles. The vacuum insulated modification represents a one-for-one component exchange within the internal non-patient contacting lumen of the cryoablation needle shaft.

Table 1 provides a comparison of the predicate and the proposed device.

Table 1 Comparison to Predicate

Description of Device	Comments related to the predicate
Design and Construction	
Needle Tip	Same
Needle Shaft	Internal one-for-one component exchange
Needle Shaft Marks	Same
Gas Pathway Tubing	Same
Handle	Same
Needle Connector	Same
Performance and Function	
Indications for Use	Same
Freezing/Thawing Technology	Same
Function	Iceball more uniform shape
Freezing Parameters	Same
Thaw Parameters	Same

Therefore as outlined in Table 1 the proposed IceSphere needles, incorporating the component exchange, have the same:

- device design (with the exception of the internal component);
- materials;
- principle of operation; and
- mechanism of action.

The component exchange does not change the functionality, intended use or the indications for use of the needles from that of the predicate non-insulated IceSphere needles.

Intended Use:

The intended use for Galil's proposed insulated IceSphere cryoablation needles ***has not changed as a result of the modification*** described in this Special 510(k). The intended use and indications for use ***are the same*** as the predicate indications for use of Galil Medical Cryoablation Systems and associated needles.

Galil Medical Cryoablation Systems are intended for cryoablative destruction of tissue during surgical procedures. The cryoablation systems are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

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 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 (ablation of arrhythmic cardiac tissue cancerous lesions)
- Proctology (ablation of benign or malignant growths of the anus or rectum, and hemorrhoids)

Summary of Performance Data and Substantial Equivalence:
Performance testing was conducted on Galil's non-insulated predicate and the proposed insulated IceSphere Cryoablation Needles 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. The insulated IceSphere successfully passed all the design properties testing in accordance with the established acceptance criteria compared to the non-insulated IceSphere predicate. Test results demonstrated that the proposed insulated IceSphere needles meet defined specifications and do not raise any new safety or effectiveness issues as compared to the predicate.

Conclusion:
Galil Medical believes the information and data provided in this Special 510(k) Notification establishes that the IceSphere needles incorporating the vacuum sleeve component do not affect safety or effectiveness, or raise different questions of safety and effectiveness from that of the predicate IceSphere 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

July 2, 2014

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

Re: K141485
Trade/Device Name: IceSphere Cryoablation Needle
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 4, 2014
Received: June 5, 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 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): K141485

Device Name: IceSphere Cryoablation Needle

Indications For Use:
Galil Medical Cryoablation Systems are intended for cryoablative destruction of tissue during surgical procedures. The cryoablation systems is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

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, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas
• ENT	Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth
• Thoracic surgery	Ablation of arrhythmic cardiac tissue cancerous lesions
• 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)

Joshua C. Nipper -S