Section 5. 510(k) Summary

FEB 6 2013

510(k) SUMMARY TEMPLATE

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

Submitter: Galil Medical Inc.
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USA

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Director, Regulatory Affairs
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Device Name: Visual-ICE® Cryoablation System, Software Revision 1.2.2

Device Classification Name: Cryosurgical unit and accessories (GEH)
21 CFR 878.4350

Predicate Device: Visual-ICE® Cryoablation System (K113860)

Device Description:

The Visual-ICE Cryoablation System is a mobile console system intended for cryoablative tissue destruction using a minimally invasive procedure. The system is computer-controlled with a touch screen user interface that allows the user to control and monitor the procedure. The therapy delivered by the system is based on the Joule-Thomson effect displayed by compressed gases. The Visual-ICE System uses high-pressure argon gas that circulates through closed-tip cryoablation needles to induce tissue freezing. Active tissue thawing is achieved by circulating helium gas through the needles or, alternatively, by the use of Galil Medical i-Thaw® technology in which a heating element inside the cryoablation needle can be energized to cause thawing.

This Special 510(k) is being submitted to modify the software with a variety of changes to enhance usability of the system. These changes are primary being made to the user interface and the service and maintenance screens. Basic functionality of the system remains unchanged, however, the following functional modifications have been made:

- Organ map display has been modified to allow users to place MTS needles on the Organ Map,
- When all channels are locked and linked together the Test All button icon state identifies the state for all channels.
- The software defaults all needles to the first 1-wire needle that was attached.

- User interface can display up to three large timers instead of two,
- Freeze-thaw cycles can now be programmed for all channels using the All button,
- The software warns the user of low gas when the remaining gas time reaches 10 minutes instead of 5 minutes,
- "Stick" intensity has been changed from 20% to 5%,
- Helium low-pressure warning was reduced to 1800 PSI from 2100 PSI.

Intended Use:
The Visual-ICE™ Cryoablation System is intended for cryoablative destruction of tissue during surgical procedures. The Visual-ICE System 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.

The Visual-ICE Cryoablation System 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 (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:
The Visual-ICE System and software were evaluated in accordance with Galil Medical's risk management plan. No new risks were identified based on the changes incorporated into Software Revision 1.2.2. A complete software verification test was conducted based on the originally approved protocol and test methods. Software Revision 1.2.2 passed all verification testing. Additional validation testing was not required based on the changes made to the software. No changes were made to the Visual-ICE System hardware.

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

Galil Medical, Incorporated
% Ms. Amy McKinney
Director, Regulatory Affairs
6518 Tamarind Sky Lane
Fulshear, Texas 77441

February 6, 2013

Re: K123865
Trade/Device Name: Visual-ICE Cryoablation System, Software Revision 1.2.2
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: January 08, 2013
Received: January 11, 2013

Dear Ms. McKinney:

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, For

Peter D. Rumm -S

Mark N. Melkerson
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): K123865

Device Name: Visual-ICE Cryoablation System, Software Revision 1.2.2

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)

Long H. Chen -S

Digitally signed by Long H. Chen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -S, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.02.06 13:32:18 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number ___K123865_____