

## Attachment 8

177 27 2006

## 510(k) Summary

**PresIce™**

**Applicant's Name:** Galil Medical Ltd.  
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Yokneam Industrial Park 20692  
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**Contact Person:** Sarit Gelbart  
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Galil Medical Ltd.  
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**Trade Name:** Presice™

**Classification:** Cryosurgical Unit  
**Common/Usual Name:** Cryosurgical unit with argon-cooled probes  
**Product Code:** GEH  
**Regulation No.:** 878.4350  
**Class:** II; FDA has not specifically classified cryosurgical units with argon cooled cryoprobes as class II devices under 21 C.F.R. § 878.4350. However, FDA has cleared Galil Medical's Cryo-Hit®, SeedNet®, SeedNetGold® and CryoThera®, which are cryosurgical units with argon-cooled Cryoprobes, as Class II devices (K980913, K991272, K991517, K993965, K003065, K010991, K012497, K011950, K021261, K031117, K042667, K051052, K052530). Therefore, cryosurgical units with argon-cooled probes are Class II medical devices.

**Predicate Devices:** Galil Medical's SeedNet® Family Systems (Cryo-Hit®, SeedNet® SeedNetGold® and Cryo-Thera®), cleared under K980913, K991272, K991517, K993965, K003065, K010991, K012497,

**Intended Use:**

Presice is intended for cryogenic destruction of tissue during surgical procedures. Presice 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.

Presice 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)

The Presice system may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure.

### **Performance Data & Substantial Equivalence:**

The modified SeedNet System (Presice) is substantially equivalent in all aspects (e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc.) to the commercially available SeedNet Family System. The principle changes between the devices include:

1. Addition of new Electrical Thaw capability (i-Thaw™), enabling a choice between two thaw operating modes, Electrical or Helium Thaw. The new Electrical Thaw mode is supported by the use of new IceRod and SeedNet Cryo Needles, the IceSeed™ i-Thaw™ and the IceRod™ i-Thaw™, comprised of a new electrical thaw mechanism in addition to the Helium based thaw mechanism used in the cleared SeedNet Family Needles. These changes were made to the modified Presice™ device alone. The existing SeedNet Family will continue to use its present hardware.
2. Addition of a Multi-Thermal Sensor (MTS).
3. Addition of touch screen user interface, thermal printer, USB port and frame grabber.
4. Change of the software programming language from LabView to C++ and C#, while implementing the changes required to support the new electrical thaw feature and improving the user interface. In addition, the company has updated the operating system to Windows XP Pro, developers environment to .NET Framework and added certain off-the-shelf software (including drivers for the touch screen, thermal printer, USB port and frame grabber) for improved system functionality. These changes were made to the modified Presice™ device alone. The existing SeedNet Family will continue to use its present software.
5. Addition of a new name, the Presice™.

Presice, the modified SeedNet Family System, and modified accessories (i-Thaw™ cryoneedles and MTS) were subjected to a comprehensive test program in order to verify their safety and performance characteristics and to demonstrate their equivalency to the cleared system and accessories. These tests included performance testing, mechanical integrity and durability testing, electrical safety and electromagnetic compatibility testing and a comprehensive validation of the modified software. Test results demonstrated that the Presice system meets its specifications and does not raise any new safety and/or effectiveness issues. Thus, the Presice system is substantially equivalent to the cleared SeedNet Family System.



FEB 21 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Galil Medical Ltd.  
c/o Mr. Jonathan S. Kahan  
Hogan & Hartson, L.L.P.  
555 Thirteenth Street, NW  
Washington, DC 20004

Re: K060390  
Trade/Device Name: Presice™  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical unit and accessories  
Regulatory Class: II (two)  
Product Code: OCL, GEH  
Dated: March 27, 2006  
Received: March 28, 2006

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of April 27, 2006.

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 (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.

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.

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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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use Statement

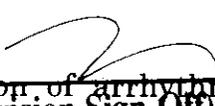
510(k) Number (if known): K060390

### Intended Use:

The Presice system is intended for cryogenic destruction of tissue during surgical procedures. The Presice 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.

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(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

K060390 (cont.)

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

The Presice System may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Prescription Use \_\_\_\_\_  
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Per 21 C.F.R. 807 Subpart C)

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
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and Neurological Devices

510(k) Number K060390