MAY 2 3 2003

K031117

SECTION 9 - 510(K) SUMMARY

510(k) Summary

Galil Medical - SeedNet™ System

510(k) Number

Company Name:

Galil Medical Ltd.

Contact Person:

Dr. Roni Zvuloni,
Director of IP & Regulatory Affairs
Telephone: +972-4-959 10 80
Fax: +972-4-959 10 77

Trade Proprietary Name:

SeedNet™ System , SeedNetGold™ System

Classification Name:

CRYOSURGICAL UNIT

Classification:

GEH

Predicate Devices:

1. SeedNet™

Indications for Use:

The SeedNet with the SmartWarmer 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 SeedNet with modified TUW 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.)

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 SeedNet System may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Technological Characteristics:

Galil Medical's SeedNet™ System with the SmartWarmer is a modification of Galil Medical LTD's cleared SeedNet™ System (K021261). The SeedNet™ System is the exact same device as the SeedNet™ except for the substitution of the SmartWarmer™ for Gaymar's warmer and Barnant's pump as the device's transurethral warmer ("TUW") accessory.

Performance Testing

Bench testing demonstrated that the SeedNet with modified TUW is at least as safe and effective as the cleared TUW in maintaining the urethra temperature during cryosurgical procedures.

Comparison to the Predicate Device

The SeedNet with the modified TUW has the same intend use, general and specific indications, and principles of operation as the cleared SeedNet™. In addition, the SeedNet with the modified TUW has the exact same technological characteristics as the cleared SeedNet except for their TUW accessories. The minor technical differences between the SeedNet with the modified TUW and the cleared SeedNet, which are primarily due to the SmartWarmer being designed specifically for use with the SeedNet while the cleared TUW contained an off-the-shelf components. Therefore, these differences do not raise any new questions of safety or effectiveness. Furthermore, performance testing demonstrates that the modified TUW is as safe and effective as the cleared TUW. Thus, the SeedNet with the modified TUW is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

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

Re: K031117
Trade/Device Name: SeedNet™ System, SeedNetGold™ System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II (two)
Product Code: OCL, GEH
Dated: April 8, 2003
Received: April 23, 2003

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of May 23, 2003.

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.

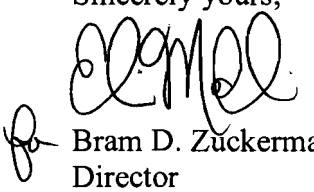
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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" (21CFR 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

Attachment 9

INDICATIONS FOR USE

510(k) Number (if known): K031117

Device Name: SeedNet™ System (SeedNet Gold™ System)

Indications for Use:

The SeedNet™ System (SeedNet Gold™ System) is intended for cryogenic destruction of tissue during surgical procedures.

It 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 SeedNet™ System (SeedNet Gold™ 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.)

ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).

Thoracic surgery (ablation of arrhythmic cardiac tissue and cancerous lesions,)

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

The SeedNet™ System (SeedNet Gold™ System) may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

(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 Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031117