# SECTION 8-510(K) SUMMARY

**510(k) Summary**

Galil Medical - SeedNet™ System

JAN 2 9 2002

**510(k) Number** K011950

**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™.**

**Classification Name:**

**CRYOSURGICAL UNIT**

**Classification:**

**GEH**

**Predicate Devices:**

1. SeedNet™
2. CRYO-HIT™
3. Cryo-Mono with TUF Probe

**Indication for Use:**

The modified SeedNet™ System is intended for cryogenic destruction of tissue during surgical procedures. is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology, 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 modified SeedNet 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 ablation of benign tumors, and palliative intervention)

Dermatology (ablation or freezing of skin cancers and other cutaneous disorders)

Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)

General surgery (destruction of warts or lesions, palliation of tumors of the oral cavity, rectum and skin, and ablation of leukoplakia of the mouth, 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, hemorroids, anal fissures, perianal conylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, and recurrent cancerous lesions)

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

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

**Technological Characteristics:**

The Galil Medical's SeedNet™ System is a modification of Galil Medical LTD's cleared SeedNet™ System with STPS (K010991). The SeedNet™ System is the exact same device as the SeedNet™ except for the following modifications to its technological characteristics:

Addition of 2 and 3 mm probes which are included in the previously cleared the Cryo-Hit™, to which the SeedNet™ is a modification.

Addition of flexible probes as an accessory to the SeedNet™.

The systems computer screens, but not its software algorithm have slightly been modified.

Substantial Equivalence

The modified SeedNet has the same intend use as the cleared SeedNet, Cryo-Hit, and Cryo-Mono with TUF Probe, the same general and specific indications as the Cryo-Hit, the same principles of operation as the cleared SeedNet, and very similar technological characteristics as the cleared SeedNet, Cryo-Hit and Cryo-Mono with TUF Probe. The minor difference in the diameter of the modified SeedNet's and Cryo-Mono's flexible probes and the modified SeedNet's computer screens does not raise any new questions of safety or effectiveness. Thus, the SeedNet™ System is substantially equivalent to these predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2002

Galil Medical Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K011950
Trade/Device Name: SeedNet™ System
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: October 30, 2001
Received: October 31, 2001

Dear Mr. Kahan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 begin 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

JAN 2 9 2002

**510(k) Number (if known):** K011950

**Device Name:** SeedNet™ System

**Indications for Use:**

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sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorroids, anal fissures, perianal conylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, and recurrent cancerous lesions)

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

(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** K011950