OCT 3 0 2001

Attachment 3

Section 8-510(k) Summary

510(k) Summary

Galil Medical - Cryo-Hit™ System

510(k) Number **K012497**

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:
Cryo-Hit™

Classification Name:
CRYOSURGICAL UNIT

Classification:
GEH

Predicate Devices:

1. CRYO-HIT™
2. Cryomedics, Neurostat
3. Spembly Lloyd Neurostat

Indication for Use:

The CRYO-HIT™ 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 CRYO-HIT™ 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 CRYO-HIT™ 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:

The Galil Medical's Cryo-Hit™ System for Cryoanalgesia is a modification of Galil Medical LTD's cleared Cryo-Hit™ (K993965). The modified Cryo-Hit™ System is the exact same device as the Cryo-Hit™ except for the addition of the 4.5 mm surface probe.

Performance Data:

The medical literature discusses the use of cryoanalgesia at least as early as 1976. FDA cleared Spembly's Neurostat for cryoanalgesia two years later. The medical literature contains data regarding hundreds of successful cryoanalgesia treatments. Thus, cryoanalgesia has a long history of safe and effective use.

Galil Medical presented two recent studies regarding the Cryo-Hit for Cryoanalgesia.

Article	**MRI Guided Percutaneous Cryotherapy of the Facet Joint Syndrome- Clinical Results with up to Two Years of Follow Up**	**Successful treatment of post-operative pain with Intercostal Cryoanalgesia following MIDCAB for coronary revascularization**
Author	J.F. ROY et al.	JD Fonger et al
Journal	Abstract for THE ISMR 9(2001)	**TO BE SUBMITTED FOR PUBLICATION**
Patient No.	48	28

Patients that received Cryoanalgesia	48	28
The Cryoanalgesia Apparatus	CRYO-HIT™	CRYO-HIT™
Gas used for freezing	Argon	Argon
Probe diameter	3mm blunt	4.5 mm surface
Monitoring method	MRI	Direct visualization of the Nerve Bundle
Median analgesia Period	11.4 months	Not reported
Complications	No major complications	No major complications
Study results	The VAS score for 88% of patients with a pure facet syndrome improved by an average of 72%. The VAS score of 53% of patients with discopathy 53% of improved by 39%. Patients with spinal fusion had a little improvement in their lower back pain.	None of the patients needed additional treatment. 62% had a mean pain score < 4 (mild pain), 31% had a mean pain score between 4 through 7 (moderate pain), and only 7% of the patients suffered from severe pain based on their VAS scores Based on a post-operative Visual Analogue Scale, 32% of the patients had no pain at all upon discharge, and 68% had only mild pain that could be treated easily with OTC drugs. None of the patients suffered any serious side effects or needed any additional intervention.
Conclusions	This study demonstrates the Cryo-Hit's safety and efficacy for administering cryoanalgesia in treatment of facet joint syndrome.	The results show that the Cryo-Hit can successfully perform Intercostal Cryoanalgesia.

These studies show that the Cryo-Hit for Cyroanalgesia is as safe and effective as the predicate devices for cryoanalgesia.

Substantial Equivalence:

The Cryo-Hit for Cryoanalgesia has the same intended use as the cleared CRYO-HIT™ System, the cleared Cryomedics Neurostat, and the cleared Spembly Lloyd Neurostat. The Cryo-Hit for Cryoanalgesia has the same general and specific indications as a combination of these predicate devices. In addition, the Cryo-Hit is the exact same device as the cleared Cryo-Hit except for the addition of a modified probe as an accessory. The modified probe does not raise any new questions of safety or effectiveness. The other technological differences between the Cryo-Hit for cryoanalgesia and the Neurostat devices also do not raise any new questions of safety or effectiveness for this indication. Moreover, clinical data demonstrates that the Cryo-Hit for Cryoanalgesia is as safe and effective as the predicate devices for this indication. Thus, the Cryo-Hit for Cryoanalgesia is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2001

Galil Medical Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K012497
Trade/Device Name: Cryo-Hit™ System
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: August 3, 2001
Received: August 3, 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,

Susan Walker, MD

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

Attachment 2

SECTION 9-INDICATIONS FOR USE

INDICATIONS FOR USE

510(k) Number (if known): K 012497

Device Name: Cryo-Hit™ System

Indications for Use: The CRYO-HIT™ System is intended for cryogenic destruction of tissue during surgical procedures.
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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 CRYO-HIT™ 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
(Per 21 CFR 801.109)

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

Over the Counter Use

510(k) Number K012497