JUL 12 1999

510(k) Summary

Galil Medical - CRYO-HIT™ System
510(k) Number K 991222

Company Name: **Galil Medical Ltd.**

Contact Person:

Shaike Schatzberger, President and CEO
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:

ENDOcare
CRYO-HIT™ System

Indication for Use:

The modified CRYO-HIT™ System, like the already cleared 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, 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.

In addition the modified 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 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)

Device Description:

The different CRYO-HIT™ models have the same performance, technology and intended use. The only difference between them are the number of probe ports available in each model (1-probe, 2-probe, 3-probe, 4-probe, 5-probe, 6-probe, 7-probe and 8-probe configurations) and the number of temperature sensor ports, to meet the needs of different customers.
The probes that can be used in the different configurations are exactly the same.
The modified CRYO-HIT™ System is the exact same device as Galil Medical LTD's cleared CRYO-HIT™ System (K980913) except for the following technological modifications: (1) Additional probes are made available; (2) single use probes are added as an option; (3) a foot pedal is added as an operating option; (4) the number of probes and external thermocouples is more varied; (5) the modified CRYO-HIT™ System allows an additional method of controlling the freeze process; and (6) minor changes to the software that are necessary for the display of the screen information.

Substantial Equivalence: The modified CRYO-HIT™ System has the same intended use, and very similar principle of operation and technological characteristic as the cleared ENDOcare and cleared CRYO-HIT™ System, thus the modified CRYO-HIT™ System is substantial equivalent to these legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 1999

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

Re: K991272
Trade Name: Cryo-Hit™ System
Regulatory Class: II
Product Code: GEH
Dated: February 17, 1999
Received: April 13, 1999

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of July 12, 1999 regarding the contact name.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 that the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K991272

Device Name: CRYO-HIT™ System

Indications for Use:

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(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 K991272

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

(Division Sign-Off)
General Restorative Devices
510(k) Number K991272