

JUL 27 1999

Galil Medical Proprietary Information

K991517
Section 9

510(K) Summary
Galil Medical - CRYO-HIT™ 200 System
510(k) Number K991517

Company Name: Galil Medical Ltd.

Contact Person: Shaik Schatzberger, President and CEO
Telephone: 972-4-959 10 80
Fax: 972-4-959 10 77

Trade Proprietary Name: CRYO-HIT™ 200

Classification: GEH

Predicate Devices: ENDOcare
CRYO-HIT™ System

Indication for Use:

The CRYO-HIT™ 200 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, tumor, lesions and warts.

In addition the CRYO-HIT™ 200 System has the following specific indications:

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Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia ("BPH"))

Oncology (ablation of cancerous or malignant tissue, 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, hemorrhoids, anal fissures, perianal conyломata, 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 CRYO-HIT™ 200 System is the exact same device as Galil Medical LTD's cleared CRYO-HIT™ System (K980913) except for the following technological modifications: (1) Additional accessories are made available (1.5 mm probe, multiprobe distribution panel). (2) disposable probes are added as an option; (3) an additional method of controlling the freeze process is offered; and (4) minor changes to the software that are necessary for the display of the screen information have been made; and (5) the probes are available in chrome-coated brass and the flexible hose is available in two additional materials.

Substantial equivalence: The CRYO-HIT™ 200 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 CRYO-HIT™ 200 System is substantially equivalent to these legally marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 1999

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

Re: K991517
Trade Name: Cryo-Hit™ 200
Regulatory Class: II
Product Code: GEH
Dated: April 17, 1999
Received: April 30, 1999

Dear Mr. Kahan:

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 (for the indications for use stated in the enclosure) 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 (Pre-market 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



/s/ 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

510(k) Number (if known): K991517

Device Name: Cryo-Hit™ 200

Indications for Use: The Cryo-Hit™ 200 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 Cryo-Hit 200 has the following specific indications:

Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia ("BPH"))

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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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

OR

Over-The-Counter Use

Handwritten signature: Kenneth A. Hogan Sr. MD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991517