AUG 12 1999

K991792

510(k) Summary
Influence, Inc.'s Cryo-Mono with TUF probe Cryogenic System
510(k) Number _____

Submitter's Name:

Peter A. Bick, M.D., President and CEO, Influence, Inc.
71 Stevenson Street, Suite 1120
San Francisco, California 94105
Telephone: 415-546-7700 / Fax: 415-546-7744

Trade Name:

Cryo-Mono Cryogenic System with TUF probe.

Classification Name:

Cryosurgical unit

Product Code:

GEH

Predicate Devices:

Galil Medical, Ltd.'s Cryo-Hit Cryogenic System, Endocare's CryoCare™ cryogenic system and Vidamed's TUNA system.

Intended Use and Indication for Use:

Influence, Inc.'s Cryo-Mono Cryogenic System and Galil Medical, Ltd.'s Cryo-Hit Cryogenic System are intended for cryogenic destruction of tissues during surgical procedures. They are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurosurgery, thoracic surgery, ENT, gynecology, oncology, proctology, and urology for the ablation of tissue, including liver metastases, skin lesions, warts, and prostate tissues. Cryo-Mono with TUF probe is specifically indicated for the ablation of prostate tissue in cases of benign prostatic hyperplasia ("BPH").

Technological Characteristics:

The Cryo-Mono is a modified version of Cryo-Hit. They have the same technological characteristics with several exceptions: The primary technological differences between the Cryo-Mono with TUF probe and the Cryo-Hit are: (1) Cryo-Mono with TUF accepts only one cryoprobe, the TUF probe, which is one of the options for the Cryo-Hit; (2) The Cryo-Mono with TUF probe is smaller than Cryo-Hit; (3) The Cryo-Mono with TUF probe has fewer gas cylinders; (4) The physician manually applies the Cryo-Mono's

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probe while with the Cryo-Hit, the physician has the option to use the "Stick" mode, which automatically adheres the probe to the tissue; (5) The Cryo-Mono with TUF probe has an optional foot pedal control; (6) The Cryo-Mono with TUF probe delivers preset amounts of argon for cooling while the Cryo-Hit adjusts the amount of argon delivered based on the tissue temperature measured by its thermocouples; (7) The Cryo-Mono with TUF probe's iceball size is monitored by transrectal ultrasound; the use of ultrasound, as well as external theromcouples, is optional with the Cryo-Hit; and (8) The Cryo-Mono's TUF probe is delivered transurethrally through a cystoscope rather than transperineally as with the Cryo-Hit.

The only modification to the device's software was the removal of the "stick" option mentioned above.

The Cryo-Mono's single-use probes are within the range of probes that can be used with the Cryo-Hit, i.e. one to eight probes.

Performance Data:

The only component of the Cryo-Mono that comes into contact with the patient's body is its cryoprobe. The biocompatibility of the Cryo-Mono is based on FDA premarket clearance of the Cryo-Hit. Its components are made of the same materials, as the Cryo-Hit's probes and Impra's Venaflo™ vascular graft. Influence has certified to the Cryo-Mono's conformance with IEC 60601-1, IEC 60601-1-2 and ASTM F882-84.

Substantial Equivalence:

The Cryo-Mono has the same general intended use and virtually identical technological characteristics as the 510(k) cleared Cryo-Hit. The minor technological differences between these devices, namely, the Cryo-Mono smaller size, use of fewer probes, lack of a "stick" option, foot pedal, modified software, fewer gas cylinders and acceptance of a transurethral flexible probe do not raise any new questions of safety and effectiveness. Thus, the Cryo-Mono is substantially equivalent to a legally marketed cryosurgical device. The Cryo-Mono with TUF probe is substantially equivalent to EndoCare's CryoCare™ in terms of its technology and indication for use. The Cryo-Mono with TUF probe is substantially equivalent also to Vidamed's TUNA system in terms of its indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Influence, Inc.
c/o Jonathan S. Kahan
Hogan & Hartson
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K991792
Trade Name: Cryo-Mono Cryogenic System with TUF Probe
Regulatory Class: II
Product Code: GEH
Dated: May 23, 1999
Received: May 26, 1999

Dear Mr. Kahan:

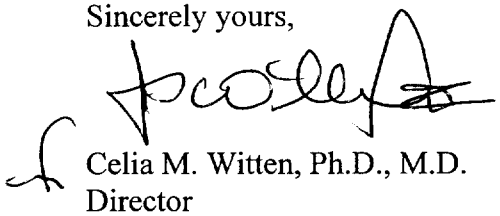
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 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,



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 STATEMENT

510(k) Number (if known): K991792

Device Name: Cryo-Mono Cryogenic System with TUF probe.

Indications for Use: The Cryo-Mono Cryogenic System is intended for cryogenic destruction of tissues during surgical procedures. It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurosurgery, thoracic surgery, ENT, gynecology, oncology, proctology, and urology for the ablation of tissue, including liver metastases, skin lesions, warts, and prostate tissues. Cryo-Mono with TUF probe is specifically indicated for the ablation of prostate tissue in cases of benign prostatic hyperplasia ("BPH").

(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 General and Restorative Devices

510(k) Number K991792

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter-Use ____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991792