JUL - 1 1999

510(k) Summary
Influence, Inc.'s Cryo-Mono Cryogenic System
510(k) Number K991122

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

Classification Name:

Cryosurgical unit

Product Code:

GEH

Predicate Devices:

Galil Medical, Ltd.'s Cryo-Hit Cryogenic System.

Intended Use and Indication 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, proctocology, and urology for the ablation of tissue, including liver metastases, skin lesions, warts, tonsils, turbinate reduction and prostate tissues. Cryo-Mono is specifically indicated for tonsil reduction in patients with blood dyscrasias or other bleeding problems and/or patients for whom general anesthesia presents an increased risk.

Technological Characteristics:

The Cryo-Mono is a modified version of Cryo-Hit. They have the same technological characteristics with several exceptions: (1) Cryo-Mono can support one cryoprobe only, while its predicate, Cryo-Hit, is capable of supporting up to 8 probes; (2) the Cryo-Mono is smaller than Cryo-Hit, (3) the Cryo-Mono has 4 gas cylinders compared to the Cryo-Hit's six; (4) Cryo-Mono software has been modified, and does not have a "Stick" option for

six; (4) Cryo-Mono software has been modified, and does not have a "Stick" option for holding the probe to the tissue during freezing; (5) Cryo-Mono can accommodate needle shaped, tonsillectomy and turbinectomy specific probes; (6) Cryo-Mono has an optional foot pedal; (7) The Cryo-Mono does not have external thermosensors, which the Cryo-Hit has; and (8) The Cryo-Mono's single-use turbinectomy and tonsillectomy cryoprobes do not have built-in thermosensors, unlike the Cryo-Hit and Cryo-Mono's multi-use probes.

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 biocompatibility of the Cryo-Mono is based on FDA premarket clearance of the Cryo-Hit. The only component of the Cryo-Mono that comes into contact with the patient's body is its cryoprobe. Its components are made of the same materials, as the Cryo-Hit's probes and Influence, Inc.'s In-Probe and In-Fast. Influence has certified to the Cryo-Mono's conformance with IEC 60601-1, IEC 60601-1-2 and ASTM F882-84. Influence has summarized representative articles in the published medical literature regarding cryotonsillectomies and cryoturbinectomies in a pre-510(k) submission concerning the device.

Substantial Equivalence:

The Cryo-Mono has the same 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 tonsillectomy and turbinectomy specific probes do not raise any new questions of safety and effectiveness. Thus, the Cryo-Mono is substantially equivalent to a legally marketed cryosurgical device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 1999

Influence, Inc.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan and Hartson, L.L.P.
Columbia Square
555 Thirteenth St., NW
Washington, D.C. 20004

Re: K991122
Trade Name: Cryo-Mono Cryogenic System
Regulatory Class: II
Product Code: GEH
Dated: March 30, 1999
Received: April 2, 1999

Dear Mr. Kahan:

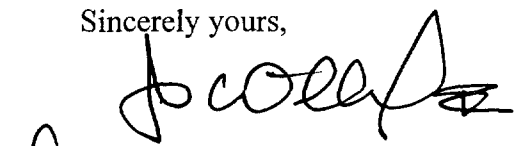
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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 STATEMENT

510(k) Number (if known): K991122

Device Name: Cryo-Mono Cryogenic System.

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, proctocology, and urology for the ablation of tissue, including liver metastases, skin lesions, warts, tonsils, turbinate reduction and prostate tissues. Cryo-Mono is specifically indicated for tonsil reduction in patients with blood dyscrasias or other bleeding problems and/or patients for whom general anesthesia presents an increased risk.

(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 K991122

Prescription Use ✓ OR Over-The-Counter-Use ____

(Per 21 CFR 801.109)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K991122