

Summary of Safety and Effectiveness

K971216

MAY 29 1997

May 19, 1997

I. Device Submitted: Cryosurgical unit and accessories

**II. Proprietary Name: Frigiderm FrigiSpray
Common Usual Name: Cryogenic Spray**

III. Predicate Device:

Frigiderm FrigiSpray marketed by DELASCO is substantially equivalent to The Brymill Cryogun manufactured by Brymill Corporation, PO Box 2392, Vernon, Connecticut 06066.

IV. Device Description:

The DELASCO Frigiderm FrigiSpray has engineered a 0.3L Vacuum Flask of stainless steel, brass and teflon for the dispensing of liquid nitrogen. The device assembly is also equipped with various size nozzles providing accessibility and a direct spray to different size lesions.

V. Intended Use:

The DELASCO Frigiderm FrigiSpray is intended to be used by Dermatologists and/or Plastic Surgeons for the following procedures.

- **Freeze destruction on epithelial arising cryoresponsive benign, premalignant and malignant tumors, such as skin tags, verrucae, cutaneous horns, actinic keratoses, and basal cell carcinoma.**

VI. Technological Characteristic Similarities:

The DELASCO Frigiderm FrigiSpray is similar in intended use and construction to the Brymill Cryogun. The Vacuum Canister composed of stainless steel is similar in design as well as the Nozzles for Liquid Nitrogen application.

VII. Performance Data:

No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). A data base search has been performed to evaluate any adverse effects of the device which is currently marketed.

No data submitted for section 807.92 6[(b)(1)(2)(3c)]

See attached documentation for adverse effects.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1997

Ms. Deborah Grafelman
Director of Marketing
Delasco
608 13th Avenue
Council Bluffs, Iowa 51501

Re: K971216
Trade Name: Frigiderm FrigiSpray
Regulatory Class: II
Product Code: GEH
Dated: April 1, 1997
Received: April 2, 1997

Dear Ms. Grafelman:

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.

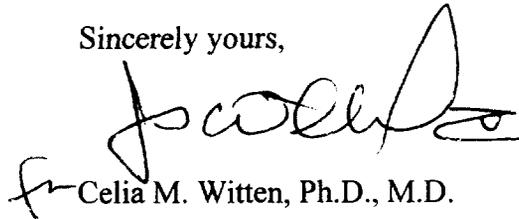
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over the typed name.

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: K971216

Device Name: Frigiderm FrigiSpray

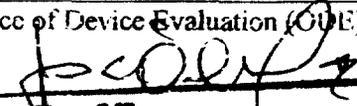
Indications for Use:

This product is intended to be used by Dermatologists and/or Plastic Surgeons for the following procedures.

Freeze destruction on epithelial arising cryoresponsive benign, premalignant and malignant tumors, such as skin tags, verrucae, cutaneous horns, actinic keratoses, and basal cell carcinoma.

(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 Restorative Devices
510(k) Number

971216

Prescription Use _____
(Per 21 CFR 801.109)