NOV 25 1998

K982280

510(K) SUMMARY

Date: June 30, 1998

Submitter: Cortex Technology ApS
Textilvaenget 1
9560 Hadsund
Denmark
45 9857-4100

Trade Name of Device Submitted: CryoPro® Mini and CryoPro® Maxi

Common Name: Cryosurgical Unit and Accessories

Classification Name: Cryosurgical Unit and Accessories (21 C.F.R. § 878.4350)

Predicate Device: The CryoPro® Mini and CryoPro® Maxi cryosurgical units are substantially equivalent to the CryoGun® liquid nitrogen cryosurgical system manufactured by Brymill Corporation. To the best of Cortex's knowledge, the CryoGun® is a "pre-amendments" device.

Device Description: The CryoPro® Mini consists of a 0.35 L stainless steel vacuum insulated, stainless steel flask equipped with a stainless steel top which holds a pressure relief valve and a dispensing valve for dispensing liquid nitrogen. The dispensing valve body is made of stainless steel with a brass valve stem and sealed with a Teflon gasket.

The dispensing valve may be mounted with spray nozzles or closed contact probes of varying sizes depending on the size and nature of the area to be treated.

The CryoPro® Maxi provides a 0.5 L stainless steel vacuum insulated flask and is otherwise identical to the CryoPro® Mini unit.

Intended Use: The CryoPro® Mini and CryoPro® Maxi units are intended to be used within the fields of dermatology and plastic surgery for the treatment of cryoresponsive benign, premalignant and malignant tumors such as skin tags, verrucae, actinic keratoses and basal cell carcinoma.

Technological Characteristics and Similarities: The CryoPro® Mini and CryoPro® Maxi units are similar in intended use, design, materials and construction to the Brymill CryoGun® units. The vacuum insulated flask is similar in design and holds the same working pressure. The relief valve, the dispensing valve, spray nozzles and contact probes are also similar in intended use, materials and construction.

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807.87(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act. . .

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

Cortex Technology APS
c/o Marsha C. Wertzberger
Counsel for Cortex Technology
Cortex Technology APS
1050 Conneticut Avenue NW
Washington, DC 20036

Re: K982280
Trade Name: Cryopro Maxi and Cryopro Mini
Regulatory Class: II
Product Code: GEH
Dated: October 16, 1998
Received: October 16, 1998

Dear Ms. Wertzberger:

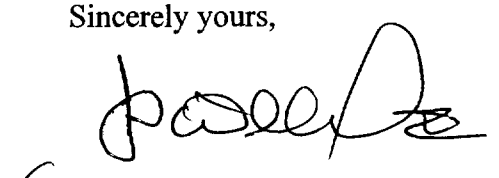
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

510(k) Number (if known):_____

Device Name: CryoPro® Maxi and CryoPro® Mini

Indications For Use:

The CryoPro® Mini and CryoPro® Maxi units are intended to be used within the fields of dermatology and plastic surgery for the treatment of cryoresponsive benign, premalignant and malignant tumors such as skin tags, verrucae, 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 K982280

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

02/13 '96 11:07