MAY 2 2 2006

K060928

1. Device Definition and Intended Use

The *CryoNeedle* Cryoprobe manufactured by Etgar Group H.M.Y.A. Ltd. (U.S Patent 6,503,246) is a hand-held cryosurgical instrument for destroying tissue during surgical procedures by intralesional application of extremely cold cryoprobe.

The device is based on intralesional application of a needle cooled by the cryogenic fluid (liquid nitrogen with boiling temperature -196°C (-320.8°F)) to a selected area to effect cellular destruction. . The needle is cooled by the cryogenic fluid (liquid nitrogen - boiling temperature -196°C (-320.8°F)) is applied intralesionally to a selected area to effect cellular destruction. By forcing liquid nitrogen to circulate through the needle an ice ball around the CryoNeedle developed causing the abutted HSK tissue to be completely frozen. As this iceball grows, its leading edge advances through tissue. Tissue that comes into contact with the iceball is destroyed. Temperatures of -25°C to -50°C (-13°F to -58°F) are achieved within 30 seconds.

The device is intended to destroy tissue during surgical procedures by applying extreme cold.

2. Substantial Equivalence (SE)

The *CryoNeedle* manufactured by Etgar Group H.M.Y.A. Ltd. is considered to be SE to the Cryoprobe™ by H&O Equipments NV/SA, Inc.

3. Consensus Standard

a. FDA has recognized consensus standard relevant to the *CryoNeedle*:

   ASTM F882-84(2002), Standard Performance and Safety Specification for Cryosurgical Medical Instruments. (General Plastic Surgery/General Hospital)

b. The modification relative to the cleared predicate device does not introduce any new hazards and does not affect the mitigations and CAPA.

4. Summary

The CryoNeedle constitutes a safe, reliable and effective medical device meeting all the declared requirements of its intended use. The device presents no adverse health effect or safety risks to patients when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2006

Etgar Group H.M.Y.A., Ltd.
c/o Mr. Benny Arazy
37a Rothschild Street, 44449
Kfar-Saba, Israel

Re: K060928
Trade/Device Name: *CryoShape*
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: January 11, 2006
Received: April 4, 2006

Dear Mr. Arazy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CryoShape - Indications For Use

510(k) Number: K060928

Device Name: *CryoShape*

Indication for Use:

The *CryoShape* is intended to destroy tissue during surgical procedures by applying extreme cold.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060928