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510(k) Summary

JUN 10 2009

As Required by 21 section 807.92 (c)

1-Submitter Name: Elbio Co. Ltd
2-Address: 517 World Meridian Venture Center II
426-5 Gasan-dong, Geumchun-gu,
Seoul, Korea
3-Phone: 82-2-744-7770 (206)
4-Fax: 82-2-744-2220
5-Contact Person: Mr Youngsam Chun (President)
6-Date summary prepared: May 24th, 2009
7- Official Correspondent: Mansour Consulting LLC
8- Address: 845 Aronson Lake Court. Roswell, GA 30075 USA
9- Phone: 678-908-8180
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President

12-Device Trade or Proprietary Name: COOLSKIN

13-Device Common or usual name: Skin cooling device

14-Device Classification Name: pack, cold, water circulating

15-Substantial Equivalency is claimed against Cryo V6.0, cleared under K060395

16-Description of the Device:

COOLSKIN is a 14" by 16" by 2 ¾ ft, 66 lb thermo-cooling mobile device that applies controlled cooling in the range of 3 degrees F to 50 degrees F (-16 degrees C to 10 degrees C) at skin surface in order to decrease skin temperature via a probe which is in direct contact with the skin surface. The device operates by semiconductor using Peltier principle. While the proximal side (towards the skin surface) gets cold, the distal side gets hot. The hot side is cooled by a water cooling system, which runs to the probe tip via a water circulating tube, and cools it. The warm/hot water is channeled away to the main unit where it is cooled via a fan. The probe is available in small and large versions.

17-Intended use of the device: (refer to FDA form attached)

This device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief of injections.

18-Safety and Effectiveness of the device:

COOLSKIN is safe and effective as the predicate device cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Elbio Company, Limited
% Mansour Consulting LLC
Mr. Jay Mansour
President
845 Aronson Lake Court
Roswell, Georgia 30075

JUN 10 2009

Re: K083008
Trade/Device Name: COOLSKIN
Regulation Number: 21 CFR 890.5720
Regulation Name: Water Circulation Hot or Cold Pack
Regulatory Class: II
Product Code: ILO
Dated: May 24, 2009
Received: June 3, 2009

Dear Mr. Mansour:

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 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); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K083008

Device Name: COOLSKIN

Indications For Use:

This device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief of injections.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mKm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083008