MAR - 7 2000

510(k) Summary

M.T.R.E. Advanced Technology Ltd.

Allon 2000 System

510(k) Number K 992386

Submitter's Name:

M.T.R.E. Advanced Technologies Ltd.
POB 3582, Caesarea Industrial Park 38900, Israel

Contact Person:

Shoshana Friedman
Push-Med Ltd.
117, Ahuza St., Ra'ananna 43373, Israel
Tel: 972-9-7718130
Fax: 972-9-7718131

Trade Name:

Allon 2000

Classification Name:

System, Thermal Regulation

Classification:

The FDA has classified these devices under Class II (product code DWJ) which are reviewed by the Division of Cardiovascular, Respiratory, and Neurological Devices.

Predicate Device:

The Allon 2000 System is substantially equivalent to the Blanketrol II System (Cincinnati Sub-Zero Products, Inc.) Cleared under A114385.

Performance Standards:

No performance standards have been established for such devices under sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the Allon 2000 System complies with the following voluntary standards: IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-35 – Part 2, IEC 68-2-13, MIL-STD-810E, IEC 68-2-6.

Indication for use:

The Allon 2000 System is intended to maintain pre-set body temperature as determined by the physician. It can also be utilized to maintain normal body temperature during surgical procedures.

The Allon 2000 System is indicated primarily for use in hospital invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical/surgical floors. This system can be used with adult and pediatric patients.

Device Description:

The Allon 2000 Hyper-Hypothermia system is used to either lower or raise a patient's temperature and/or maintain a desired patient temperature using a garment, which is wrapped around the body during and after surgery to achieve maximum coverage. This, for example, minimizes the tendency of the body to cool down as a result of anesthesia and exposure. The garment can be configured to cover any surface area of the patient's body and yet not to interfere with areas that must be exposed during surgery. As a flow of cooled or heated water is forced through the garment by the pump of the Allon 2000 System, the heat is exchanged with the body. The water temperature is controlled and maintained at any temperature between 59 and 104.3°F (15 - 40.2°C) using a feedback loop based on surface and core thermostat sensor readings.

Safety and Effectiveness:

The electrical and electromagnetic safety of the Allon 2000 as been proven to meet the IEC 60601 and IEC 60602 standard through in-vitro tests. The Allon 2000 software and software applications have been verified and validated. The biological safety of the Allon 2000 garment has been assured through biocompatibility studies. The effective performance of the Allon 2000 System has been established through in vitro, animal and clinical studies.

Substantial Equivalence:

Based on a series of safety and performance testing, including animal and clinical studies, we believe that the Allon 2000 System is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2000

Ms. Shoshana Friedman, RAC
MTRE Advanced Technology, LTD.
117 Ahuza Street
Ra'ananna 43373
Israel

Re: K992386/S1
Allon 2000
Regulatory Class: II (two)
Product Code: DWJ
Dated: December 15, 1999
Received: December 16, 1999

Dear Ms. Friedman:

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) 594-4648. 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" (21CFR 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.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number K992386

Device Name: Allon 2000 System

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(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992386