M.T.R.E. Advanced Technology, Ltd.
POB 26, Or Akiva Industrial Park
Or Akiva, Israel 30600
Tel - [972] 4-6108000
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FEB 1 0 2003

2.1 Summary of Safety and Effectiveness

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Tel - 011-972-4-6108000
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Official Contact: Shlomi Deler, QA/RA Manager

Proprietary or Trade Name: Allon 2001 version 5

Common/Usual Name: Thermal Regulating System

Classification Name: Thermal Regulating System

Device: Allon 2001 version 5

Predicate Devices: M.T.R.E. - Allon 2001 – K003349
Cincinnati Subzero – Blanketrol II - preamendment.

Device Description:

The ***Allon 2001 vesion 5*** system consists of the following elements:

- Temperature controlled disposable garment
- Body sensors
- Connecting flexible water pipes
- Heating/Cooling Unit

The system is operated by circulating water by a pump in a closed loop between the device and a disposable garment worn by the patient. The water circulates through the heating/ cooling unit. Temperature (body) sensors are placed on the patient and in the rectum, nasopharynx or esophageal to measure core temperature. The operator selects the desired patient core temperature and the unit operates in an automatic mode. Patient temperature is controlled and maintained at any set point between 30-40°C using a feedback loop and sensors placed on the patient's body.

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The heating/cooling unit is based on a solid-state thermo-electric device, which operates as a heat pump. The system is intrinsically safe, due to the characteristics of the thermo-electric device, heating capacity drops off as the Thermo Electro Cooler (TEC) temperature rises. Hence, if for any reason, flow of coolant is interrupted, the TEC will overheat and the power output will fall, thus limiting water temperature rise.

The disposable garment is provided in a variety of shapes and sizes, which are manufactured of the same materials and by the same process as those already cleared under K001546, K992386 and K003349.

Intended Use:

Indication for use-- The Allon 2001 version 5 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. This system can be used with adult and pediatric patients.

Environment of Use -- Hospital, invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors

Contraindications-- The Allon 2001 version 5 system should not be in direct contact with open, widespread skin lesions such as burns or dermatitis. The safety and effectiveness of use of the Allon2001 version 5 on patients with multiple traumas has not been established.

Comparison to Predicate Devices:

	Allon 2001 / CSZ – Blanketrol K003349 Preamendment	***Allon 2001 version 5***
Equipment Design		
Dimensions	26cm X 53cm X 52cm	26cm W X 62.5cm D X 94cm H
Weight	33 Kg (without water in the reservoir)	The same
Mobility	Mobile with four wheels.	The same
Power max.	500 W max.	The same
Input power	120/230 V ac with isolation transformer	The same
Water tank	6 liter	The same

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	*Allon 2001 / **CSZ – Blanketrol*** *K003349* ***Preamendment***	***Allon 2001 version 5***
HCU	Thermo Electro Cooler based on Peltier effect.	The same
Control System		
Water out temp'	13-40.8 °C	The same
Set Point temp'	30-40 °C	The same
Flow rate	0.2-1.25Lpm	The same
Pressure rate	0.1-1.3 bar	The same
Safety System		
High primary	41 °C / **CSZ - 45 °C**	42 °C
High secondary	42°C / **CSZ - 46 °C**	44 °C
High third	44 °C / **CSZ - N/A**	N/A
Low primary	10 °C	The same
Pressure valve	Yes	The same
Safety Alert / Alarms		
Dislodged sensor	Yes	The same
Incorrect Patient temp' setting	Yes	The same
High/Low patient temp' limit.	Yes	The same
Out of normothermia	Yes	The same
High/Low water temp' limit	Yes	The same
Low water	Yes	The same
Low water flow	Yes	The same
Water blocking	Yes	The same
Non – Operating Pump	Yes	The same
Monitoring/indicators		
Water out temp'	Yes	The same
Not enough water in tank	Yes	The same
Water in temp'	Yes	The same
Patient Surface Temp.	Yes	The same
Patient core Temp.	Yes	The same
Water pressure	Yes	The same
Graphic presentation. Patient temp During treatment	Yes	Modified , after changing machine interface lay-out display

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	Allon 2001 / CSZ – Blanketrol K003349 Preamendment	*Allon 2001- modified*
Operating Buttons		
Set Point temp'	Yes	The same
Silence Alarm	Yes	The same

Discussion of Substantial Equivalence to Legally Marketed Predicate Devices

The Allon 2001 version 5 system is viewed as substantially equivalent to the following predicate devices - Allon 2001 system cleared under K003349, and Cincinnati Subzero – Blanketrol - preamendment.

There are no significant differences between the Allon 2001 version 5 and the Allon 2001 and Cincinnati Subzero – Blanketrol, the predicate devices, that affect the safety or effectiveness of the intended device as compared to the predicate devices. Allon 2001 version 5 is viewed as substantially equivalent to the predicate devices since they:

1. Have the same intended use
    - 1.1 Maintain pre-set body temperature as determined by the physician.
    - 1.2 Maintain normal body temperature during surgical procedures.
2. Have the same environment for use
    - 2.1 Are used in hospitals, invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors,
    - 2.2 Have been designed for stationary and intra-institution transport only.
3. Are similar in design
4. Employ the same technology
5. Are made of identical materials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2003

M.T.R.E. Advanced Technology, Ltd.
c/o Mr. Douglas Rash
President
M.T.R.E. North America, Inc.
6052 Wilmington Pick #225
Centerville, OH 45459

Re: K024128
Trade Name: Allon 2001 Version 5
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulation System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: January 20, 2003
Received: January 27, 2003

Dear Mr. Rash:

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 (301) 594-4646. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

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Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: K024128 (To be assigned)

Device Name: Allon 2001 version 5

Intended Use The Allon 2001 version 5 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. It is indicated 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024128

Prescription Use X or **Over-the-counter use** __
(Per CFR 801.109)