K120860

MAY - 8 2012

5 510(k) Summary – Traditional Submission

This 510(k) summary of Safety and Effectiveness is submitted as part of the PreMarket Notification in accordance with the requirements of 21CRF 807.92.

5.1 510(k) Submitter

Name:	Medical Rescue Equipment Holding A/S
Address:	Kjolnes Ring 30 3918 Porsgrunn Norway
Phone:	0047-90610425
Fax:	0047-35515014

5.2 Contact Information

Name:	Mr. Knut Fangberget
Address:	Kjolnes Ring 30 3918 Porsgrunn Norway
Phone:	0047-9156 1581
Fax:	0047-35515014

5.3 Date of Preparation

August, 2010

5.4 Identification of the Device

1. Trade Name: INFU Box Type 0412A
2. Common Name: IV fluid warmer
3. Classification Name: Warmer, Thermal, Infusion fluid
4. Product code: LGZ

5.5 Predicate Devices

Soft Sack, FloorMount and Pak 2, IV warmer devices (K060851) and Bair Hugger® Blood/Fluid Warmer (K973741)

5.6 Indications for Use

The INFU Box is indicated for the regulation of temperature of intravenous (IV) fluid bags prior to administration. The device is intended for bags with crystalloid fluids only. Intended users are health care professionals. The device is intended for use in clinical and field environments and is intended to be mounted in a ground based field operating

vehicle, such as ambulance or military vehicle.

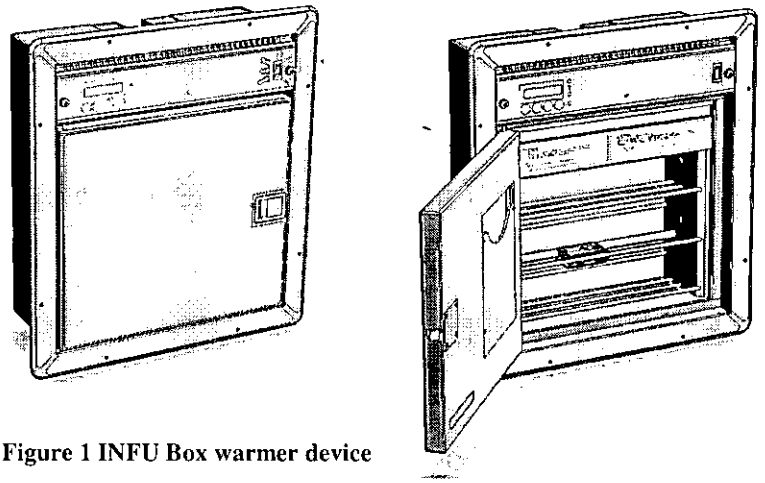

Figure 1 INFU Box warmer device

5.7 Description of Device

The INFU box warmer device is electronically regulated to obtain and maintain a preset temperature. Electronically controlled Peltier elements are used to produce a temperature difference between an internal and external airflow. The device uses environmental air to regulate the temperature. It is designed to maintain three 1000 ml IV liquid bags.
The main system is powered by a 12 V DC source.

The device meets the applicable requirements of IEC 60601-1-1, IEC 60601-1-2 and SS-EN 1789:2007.

5.8 Comparison with Legally Marketed Predicate Devices

The INFU Box is similar to the predicate devices in that:

1. The systems are intended for the warming of IV fluids prior to administration, and intended users are designated to be healthcare professionals.
2. The systems use electronically temperature regulation for IV liquids, just as INFU Box.
3. The systems are intended for field and clinical applications.
4. The systems provides with alarms for over-temp.

The INFU Box differs from the predicate devices in that:

1. The Bair Hugger can also operate with blood products, and is an "in-line" warming system. The INFU Box is not intended to provide this feature.
2. INFU Box is intended to be *mounted* in a ground based vehicle or hospital/ nursing centre, why mechanical robustness and portability demands are different on this product.

To support information of substantial equivalence and to follow up risk management, a number of bench tests have been performed. These tests give evidence to the fact that the INFU Box device indeed is safe and effective in providing with a regulation of the temperature of IV fluid bags prior to administration.

5.9 Conclusion

The INFU Box device is substantially equivalent to the identified legally marketed devices intended for use in warming IV bags containing crystalloid fluids bags, using conduction from an external electronic component.

The potential hazards have been studied and controlled as a part of the product development process, including risk analysis, test and design consideration, and planned verification and validation testing processes. The INFU Box is intended for use in clinical and field environments comparable to the predicate devices.

Based on a comparison of the performance characteristics and the results from the tests, it is concluded that the INFU Box is substantial equivalent to the predicate devices and therefore safe and effective for its intended use.

Table 1: Summary of performed tests

Type of test/-s	Place of testing	Result	References
Mechanical tests -vibration & chock EN 1789:2007; Applicable parts: • IEC 60068-2-6; Test Fc • IEC 60068-2-64; Test Fh • IEC 60068-2-27; Test Ea/Eb	CECert GmbH	Tests showed that the device is safe for exposition of normal vibration and chock in ambulance vehicles. –Free fall test not necessary since device is stationary mounted.	Appendix L
IP tests IEC 60529:1992+A1:2000 +Corrigendum 2:2007+Corrigendum 3:2009	SP -Technical Research Institute of Sweden	The device was classified and marked to class IP20.	Appendix H (Test ID MR-5)

Climatic tests -according to specified intended use • IEC 60068-2-1 test Ab • IEC 60068-2-2 test Bb • IEC 60068-2-78 test Cab	SP -Technical Research Institute of Sweden	The tests showed that the device works as specified in intended use temperature and after storage in permitted storage/shipping temperature and humidity.	Appendix K Appendix A
Effectiveness of intended use	Hotswap Jönköping AB -Internal tests at engineering consultant company.	Tests showed that error messages and signals works, that the device is effective –(target temperature is reached +/- 2°C in 2-4h). Manual and other labeling follows demands and contains all information and warnings. All materials are corrosion free.	Appendix H (other tests are also included in document)
EMC IEC 60601-1-2	CECert GmbH	The device passed the EMC requirements and is safe considering EMC, in terms of conducted and radiated emission and electric fields, disturbance etc.	Appendix I
Electrical Safety IEC 60601-1	CECert GmbH	Electromagnetic compatibility was tested to be ok, see above. Protection, hazards etc were tested. In the first test some did not pass and were treated in document Appendix M Design update report and decided to have been adjusted to	Appendix J Appendix M Appendix N

		comply to requirements. A complementary test was made and passed, Appendix N.	
User studies	Internal –Personnel from MRE & field study	Some devices were field tested in a winter practice with military care personnel. These test results have not been included as result in application, but have given input about user interface and field findings for manufacturer.	Not included in application.

Further information in referenced documents and in 018_"Performance Testing –Bench".

End of 510(k) summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Knut Fangberget
Medical Rescue Equipment Holding A/S
Postboks 186
Porsgrunn
Norway 3901

MAY - 8 2012

Re: K120860
Trade/Device Name: INFU Box Type 0412A
Regulation Number: Unclassified
Regulation Name: Warmer, Thermal, Infusion Fluid
Regulatory Class: II
Product Code: LGZ
Dated: March 22, 2012
Received: March 22, 2012

Dear Mr. Fangberget:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

Applicant: Medical Rescue Equipment Holding AS

510(k) Number (if known): _____

Device Name: INFU Box Type 0412A

Indications for Use:

The INFU Box is indicated for the regulation of temperature of intravenous (IV) fluids bags prior to administration. The device is intended for bags with crystalloid fluids only. Intended users are health care professionals. The device is intended for use in clinical and field environments and is intended to be mounted in a ground based field operating vehicle, such as ambulance or military vehicle.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120860