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K101705

510(k) Summary

JUL - 2 2010

Applicant:

The Surgical Company International BV (TSCI)
Beeldschermweg 6F
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The Netherlands

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Date Prepared: 25 January 2010

Device name:

Proprietary Name: Mistral-Air Warming System
Common/Usual Name: Heating pad control unit, air: (GMDN-code: P 36954)
Heating pad system under/overlay, air (GMDN-code: P 36931)
Classification Name: Thermal regulating system (21 CFR 870.5900)
Product Code: DWJ

Predicates:

- Soft-Air Patient Warming System Model SA 4000 [K073712]
- Bair Hugger Model 750 Total Temperature Management System [K001149]
- CSZ WarmAir Hyperthermia System [K942599 and K942790]

Device description:

The Mistral-Air Warming System comprises of the following devices:

- MA1100-US Mistral-Air Plus Warming Unit 110-120V~, 60Hz
- MA0220 Mistral-Air Adult Blanket (white)
- MA0230 Mistral-Air Paediatric Blanket (white)
- MA0250 Mistral-Air Lower Body Blanket (white)
- MA0260 Mistral-Air Upper Body Blanket (white)
- MA0265 Mistral-Air Half Upper Body Blanket (white)
- MA0270 Mistral-Air Torso Blanket (white)
- MA0280 Mistral-Air Full Body Surgical Access - Sterile (white)
- MA0290 Mistral-Air Full Body Surgical Access - Non-sterile (white)
- MA0320 Mistral-Air Adult Blanket (silver)
- MA0330 Mistral-Air Paediatric Blanket (silver)
- MA0340 Mistral-Air Neonatal Blanket (silver)
- MA0350 Mistral-Air Lower Body Blanket (silver)
- MA0360 Mistral-Air Upper Body Blanket (silver)
- MA0365 Mistral-Air Half Upper Body Blanket (silver)
- MA0400 Mistral-Air Full Underbody (silver)
- MA0450 Mistral-Air Underbody (silver)
- MA0510 Mistral-Air Tube (blue)

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Intended use:

The Mistral-Air Warming System is a forced air warming device and comprises of a warming unit and a variety of blankets. It is intended to raise and maintain patient temperature by means of surface warming.

The principle of operation is an electrically powered unit (the Mistral-Air Plus Warming Unit) consisting of a fan and heating element that propels warmed air via a flexible hose to a blanket (the Mistral-Air Blanket) draped over the patient. Some configurations allow for the patient to be placed on top of the blanket or surrounded by a warming tube. Almost all types of Mistral-Air Blankets types are provided non-sterile. However, one type of Mistral-Air Blankets is provided sterile. The Mistral-Air Blankets (both non-sterile and sterile versions) are intended for single patient use only.

Technological characteristics:

The main technological characteristics of the Mistral-Air Plus Warming Unit are:

- Materials: metal, electronics and ABS.
- Air filter: HEPA
- Motor: Single phase AC, 75 W
- Heater: 1000W resistive
- Control circuitry: microprocessor-based

The main technological characteristics of the Mistral-Air Blankets are:

- Materials: polypropylene and polyethylene.

These and other technological characteristics are the same or similar as the predicate devices.

Summary of the main non-clinical tests and results:

In order to verify the performance of the Mistral-Air Warming System the following bench tests were conducted:

- Air flow performance
- Air pressure performance
- Filtering performance
- Temperature performance
- Endurance test
- Extreme Temperatures
- Keyboard test

It was demonstrated that the Mistral-Air Warming System is in compliance with the set performance specifications.

Conclusion:

The Mistral-Air Warming System has the same intended use and performance as the predicate devices. Therefore, The Surgical Company International BV believes these proposed devices do not raise any new safety or effectiveness issues.

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

The Surgical Company International B.V.
c/o Mr. Casey Conry
Underwriters Laboratories Inc.
1285 Walt Whitman Rd
Melville, NY 11747

JUL - 2 2010

Re: K101705
Trade/Device Name: Mistral Air Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: June 16, 2010
Received: June 17, 2010

Dear Mr. Conry:

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,

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

Enclosure

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Indications for Use Statement

510(k) Number: to be determined

Device Name: Mistral-Air® Warming System

Indications for Use: The Mistral-Air® Warming System is a forced air warming device and comprises of a warming unit and a variety of blankets. It is intended to raise and maintain patient temperature by means of surface warming.

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 Cardiovascular Devices

510(k) Number K101705