DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 26, 2017

The Surgical Company International BV
c/o Dave Yungvirt
Third Party Review Group, LLC
24 Lackawanna Place
Millburn, NJ 07041

Re: K171234
Trade/Device Name: Mistral-Air Warming Unit
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: April 26, 2017
Received: April 27, 2017

Dear Dave Yungvirt:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Fernando Aguel -S

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

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171234

Device Name
Mistral-Air® Warming System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Applicant:

510(k) owner's name:	The Surgical Company International BV (doing business as The 37Company)
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Date prepared:	April 21, 2017

Device name:

Proprietary Name:	Mistral-Air® Warming System
Common/usual name:	Forced air warming system, an comprises of: Mistral-Air® - SYK, Forced Air Warming unit: circulating-air whole-body heating system control unit: (GMDN-code: 36954) Mistral-Air® warming blanket (non-sterile): Circulating-air whole-body heating/cooling system pad, single-use, non-sterile (GMDN code: 47681) Mistral-Air® warming blanket (sterile): Circulating-air whole-body heating/cooling system pad, single use, sterile (GMDN-code: 47682)
Regulation number:	21 CFR 870.5900
Regulation Description:	Thermal regulating system
Device class:	Class II
Product Code:	DWJ

Predicate:

- [K101705] Mistral-Air® Warming System

Regulation number:	21 CFR 870.5900
Regulation Description	Thermal regulating system.
Device class:	Class II
Product Code:	DWJ

Device description:

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

- One warming unit of models:
  - MA1200-PM Mistral-Air® - SYK (forced air warming unit 100-125 V~, 50/60 Hz)

Connected to

- One warming blanket of models:

Non-sterile Accessory:
Stryker REF / Stryker Proprietary name
MA02010-PM Faceshield - SYK

Non-sterile blankets:
Stryker REF / Stryker Proprietary name
MA0220-PM / Adult White - SYK
MA0230-PM / Paediatric White - SYK
MA0250-PM / Lower Body White - SYK
MA0260-PM / Upper Body White - SYK
MA0265-PM / Half Upper Body White - SYK
MA0270-PM / Torso White - SYK
MA0290-PM / Surgical Access White - SYK
MA0320-PM / Adult Reflective - SYK
MA0330-PM / Paediatric Reflective - SYK
MA0340-PM / Neonatal Reflective - SYK
MA0350-PM / Lower Body Reflective - SYK
MA0360-PM / Upper Body Reflective - SYK
MA0365-PM / Half Upper Body Reflective - SYK
MA0400-PM / Full Underbody Reflective - SYK
MA0450-PM / Underbody Reflective - SYK
MA0510-PM / Tube - SYK

Sterile blankets:
Stryker REF / Stryker Proprietary name
MA0280-PM / Surgical Access White (sterile) - SYK
MA0285A-PM / Lower Surgical Access White (sterile) - SYK
MA0286-PM / Cardiac Blanket (sterile) - SYK

Non-sterile blankets:
Stryker REF / Stryker Proprietary name
MA1610-PM / Premium Warming Suit S - SYK
MA1620-PM / Premium Warming Suit M - SYK
MA1630-PM / Premium Warming Suit L - SYK
MA1640-PM / Premium Warming Suit XL - SYK
MA1710-PM / Warming Suit S - SYK
MA1720-PM / Warming Suit M - SYK
MA1730-PM / Warming Suit L - SYK
MA1740-PM / Warming Suit XL - SYK

Non-sterile blankets:
Stryker REF / Stryker Proprietary name
MA2220-PM / Adult Plus - SYK
MA2230-PM / Paediatric Plus - SYK
MA2240-PM / Neonatal Plus - SYK
MA2250-PM / Lower Body Plus - SYK
MA2260-PM / Upper Body Plus - SYK

MA2265-PM / Half Upper Body Plus - SYK
MA2270-PM / Torso Plus - SYK
MA2290-PM / Surgical Access Plus - SYK
MA2400-PM / Full Underbody Plus - SYK
MA2450-PM / Half Underbody Plus - SYK
MA2475-PM / Paediatric Underbody Plus - SYK
MA3320-PM / Premium Adult - SYK
MA3330-PM / Premium Paediatric - SYK
MA3340-PM / Premium Neonatal - SYK
MA3350-PM / Premium Lower Body - SYK
MA3360-PM / Premium Upper Body - SYK
MA3365-PM / Premium Half Upper Body - SYK
MA3400-PM / Premium Full Underbody - SYK
MA3450-PM / Premium Half Underbody - SYK
MA3475-PM / Premium Paediatric Underbody - SYK

Sterile blankets:
Stryker REF / Stryker Proprietary name
MA2280-PM / Surgical Access Plus (sterile) - SYK
MA2285-PM / Lower Surgical Access Plus (sterile) - SYK
MA2286-PM / Cardiac Blanket Plus (sterile) - SYK

The principle of operation is an electrically powered forced air warming unit (consists of a control circuit, an air filter, a fan, a heating element and temperature sensors) that propels warmed air via a flexible hose to a warming blanket (sterile or non-sterile, depending on the model) draped over the patient. Some warming blankets allow for the patient to be placed on top of the blanket or surrounded by a warming tube. All warming blankets are intended for single patient use only.

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.

Technological characteristics:

The main technological characteristics of the Mistral-Air® warming unit are:

- Materials: metal, electronics and ABS/PC.
- Air filter material: HEPA
- Motor: single phase AC powered
- Heater: 1000W resistive
- Control circuitry: microprocessor-based

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

- Materials: polypropylene and polyethylene (and aluminium and polyurethane for reflective blankets).

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 and the standards in Table 1.

Table 1 Standards where the Mistral-Air® warming system complies with.

Number/code	Title	Version	Pass/Fail
AAMI/ANSI ES60601-1	Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance (edition 3.1; FDA rec. # 19-4)	2005/(R)2012 + A1:2012 + C1:2009/(r)2012 + A2:2010/(r)2012	Pass
IEC 60601-1-2	Medical electrical equipment - Part 1-2: Collateral Standard: Electromagnetic Compatibility - Requirements and tests (edition 3.0; FDA rec. # 19-1)	2007	Pass
IEC 60601-1-6	Medical electrical equipment - Part 1-6: Collateral Standard: Usability (edition 3.1; FDA rec. # 5-89)	2010 + A1:2013	Pass
IEC 60601-1-8	Medical electrical equipment - Part 1-8: Collateral Standard: Requirements and Tests and Guidance for Alarm Systems in Medical Electrical Equipment (edition 2.1; FDA rec. # 5-76)	2006 + A1:2012	Pass
IEC 62304	Medical Device Software - Software Life Cycle Processes (edition 1.0; FDA rec. # 13-92)	2006	Pass
IEC 62366-1	Medical devices - Application of usability engineering to medical devices (edition 1.0; FDA rec. # 5-95)	2015	Pass
IEC 60529	Degrees of protection by enclosures (IP Code) (edition 2.1)	2001	Pass
IEC 80601-2-35	Medical Electrical Equipment - Part 2-35: Particular Requirements for the Basic Safety and Essential Performance of Heating Devices using Blankets, Pads or Mattresses and Intended for Heating in Medical Use (Edition 2.1)	2016	Pass
ISTA 3A	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less (FDA rec. #: 5-110)	2008	Pass
ASTM D4169	Standard practice of performance testing of shipping containers and systems (FDA rec. #: 14-462)	2014	Pass
ASTM D642	Standard test method for determining compressive resistance of shipping containers, components and unit loads	2000	Pass
ISO 10993-1	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process (FDA rec. #: 2-156)	2009/(R)2013	Pass
ISO 11135	Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices (FDA rec. #: 14-452)	2016	Pass

Conclusion:

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