August 7, 2026

The Surgical Company International B.V., doing business as TSC Life
Gianpaolo Soares
RA Project Manager
Paalbergweg 3
Noord-Holland
Amsterdam, 1105 AG
Netherlands

Re: K261437
Trade/Device Name: Mistral-Air® Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: July 10, 2026
Received: July 10, 2026

Dear Gianpaolo Soares:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KATHLEEN M. GRUNDER -S

for Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261437

Please provide the device trade name(s).

Mistral-Air® Warming System

Please provide your Indications for Use below.

The Mistral-Air® Warming System is indicated for patient warming in situations where prevention of inadvertent hypothermia is required.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

TSC LIFE

Innovation with purpose

Submitter Name and Address	The Surgical Company International B.V., doing business as TSC Life Paalbergweg 3 Amsterdam, 1105 AG The Netherlands
Contact Person	Name: Gianpaolo Soares Title: Regulatory Affairs Project Manager, TSC Life Company Telephone: 765-205-6030 Email: fda.tsclife-us@tsc-life.com
Device Information	Name of Device: Mistral-Air® Warming System Model: MA1400 (Warming Unit) Common or Usual Name: Thermal regulating system Classification Name: System, Thermal Regulating, 21 CFR 870.5900 Regulatory Class: II Product Code: DWJ
Predicate Information	*Same device as required for Special 510(k) pathway.* Name of Predicate: Mistral-Air® Warming System Model: MA1200 (Warming Unit) 510(k) Number: K171234 This predicate has not been subject to a design-related recall. No reference devices were used in this submission.
Device Description	The Mistral-Air® Warming System is comprised of a warming unit and blankets and is designed to warm patients using temperature-controlled filtered warm forced airflow. The device's blanket, which can be placed on top, around, or underneath a patient, guides the airflow towards the skin of the patient, where heat is transferred by convection. Additionally, this combination keeps the patient insulated. The warming unit generates and directs the warm air into the blankets. This controlled airflow ensures consistent and effective warming. For optimal safety and performance, warming unit and hose shall only be used with the Mistral-Air® blankets.
Intended Use	The Mistral-Air® Warming System is a forced air warming system that comprises of a warming unit and a variety of blankets. It is intended to raise and maintain patient temperature by means of surface warming.
Indications for Use	The Mistral-Air® Warming System is indicated for patient warming in situations where prevention of inadvertent hypothermia is required.

Table 1: Comparison of Technological Characteristics

Subject	Predicate Device Mistral-Air® Warming System (with MA1200)	Subject Device Mistral-Air® Warming System (with MA1400)	Substantial Equivalence
Mode of Operation	Manual operation via control panel	Manual operation via control panel	Same
Material of Mistral-Air® Warming Unit	Metal, electronics and ABS/PC	Metal, electronics and ABS/PC	Same
Operating Principle	Electrically powered device (consisting of a control circuit, air filter, fan, heating element and temperature sensors) that propels warmed air via a flexible hose to a blanket (Sterile or Non-sterile, depending on the model) draped on or under the patient.	Electrically powered device (consisting of a control circuit, air filter, fan, heating element and temperature sensors) that propels warmed air via a flexible hose to a blanket (Sterile or Non-sterile, depending on the model) draped on or under the patient.	Same
System Components	• Reuseable Warming unit • Disposable sterile and non-sterile blankets/suits	• Reuseable Warming unit • Disposable sterile and non-sterile blankets/suits	Same
Warming Technology	Convection	Convection	Same
Energy Source	100-125 V AC, 50Hz/60Hz	100-125 V AC, 50Hz/60Hz	Same
Blanket Compatibility	Yes - Compatible with Mistral-Air® Warming Blankets	Yes - Compatible with Mistral-Air® Warming Blankets	Same

Performance Data

Nonclinical safety data included electrical safety and electromagnetic compatibility evaluation, software verification and validation, mechanical and durability assessments, lifecycle and packaging evaluations, human factors evaluation, and risk management activities. Cybersecurity documentation was prepared in accordance with FDA's guidance 'Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions' (issued February 3, 2026).

Conclusion

The purpose of this Special 510(k) premarket notification is to introduce a new model of the Mistral-Air® Warming Unit (part of the Mistral-Air® Warming System). The results of the nonclinical evaluations conducted for this premarket notification demonstrate that the modified device is as safe and as effective as the legally marketed predicate device and performs as well as or better than the predicate. The proposed model change does not alter the device's intended use or fundamental technological characteristics, nor does it raise new questions of safety or effectiveness. The information provided supports a determination that the Mistral-Air® Warming System, including the MA1400 Warming Unit, is substantially equivalent to the predicate Mistral-Air® Warming System with the MA1200 Warming Unit cleared under K171234.