The Surgical Company International BV (as TSC Life)
Gianpaolo Soares
Regulatory Affairs Project Manager
Paalbergweg 3
Amsterdam, North Hollans 1105 AG
Netherlands

Re: K251733
Trade/Device Name: Fluido® AirGuard System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ, FRN
Dated: June 4, 2025
Received: June 6, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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.	
Please provide the device trade name(s).	

Fluido® AirGuard System

Please provide your Indications for Use below.

• Infusion of crystalloid, colloid or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.
• Infusion of warmed fluid to patients with the ability to prevent hypothermia.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

(in accordance with 21 CFR 807.92)

Fluido® AirGuard System

June 2025

Submitter Name and Address	The Surgical Company International B.V., doing business as TSC Life Bedrijvenpark Twente Noord 48, 7602 KR Almelo, Netherlands
Contact Person	Name: Gianpaolo Soares Title: Regulatory Affairs Project Manager Telephone: +31 642771951 Email: fda.tsclife-us@tsc-life.com
Device Information	Name of Device: Fluido® AirGuard System Common or Usual Name: Infusion Pump Classification Name: Infusion Pump, 21 CFR 880.5725 Regulatory Class: II Product Code: LGZ
Predicate Information	Name of Predicate: The Belmont® Rapid Infuser, RI2 510k Number: K141654 This predicate has not been subject to a design-related recall. Name of Reference Device: Ranger Irrigation Fluid Warming System 510k Number: K060939

Device Description

The Fluido® AirGuard System (FAS) is a pressurized infusion system intended for warming blood and fluids prior to administration to help prevent perioperative hypothermia. The FAS uses infrared heating technology to safely warm blood and fluids; the system detects air to prevent it from entering the patient.
The FAS consists of the Fluido Pressure Chambers, Fluido Blood and Fluid Warmer, Fluido AirGuard, Fluido Compressor, Fluido IV Pole, and Fluido Single-Use (Disposables): Standard Set and Trauma Set.

Component	Functionality
Pressure Chambers	Hold the IV fluid or blood bags and control the flow of the fluid by increasing or decreasing the pressure.
Blood and Fluid Warmer	Warms the blood or fluid to the set temperature.
AirGuard	Monitors the blood or fluid for the presence of air and prevents it from reaching the patient.
IV Pole	Ensures a stable operating platform for the system.
Compressor	Supplies pressurized air to the Pressure Chambers.
Disposables	Define a sterile pathway for the blood and fluids to be administered to the patient, with adjustable flow rates. Allows for manual air removal.

Indications for Use

- Infusion of crystalloid, colloid or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.
- Infusion of warmed fluid to patients with the ability to prevent hypothermia.

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1. Comparison of Technological Characteristics with the Predicate Device

Table 1 Comparison of Fluido AirGuard System to Belmont Rapid Infuser RI2

Features	Subject Device Fluido AirGuard System (FAS)	Predicate Device Belmont Rapid Infuser RI2 (K141654)	Reference Device Ranger Irrigation Fluid Warming System (K060939)	Summary
Manufacturer	The Surgical Company International B.V. (TSC Life)	Belmont Instrument Corporation	Formerly: Arizant Healthcare, Incorporated Currently: 3M Health Care	Not applicable
Regulation Name	Infusion Pump	Infusion Pump	Infusion Pump	Not applicable
Regulation Number	21 CFR 880.5725	21 CFR 880.5725	21 CFR 880.5725	Not applicable
Product Code	LGZ	FRN, LGZ	LGZ	Not applicable
Indications for Use	• Infusion of crystalloid, colloid or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery. • Infusion of warmed fluid to patients with the ability to prevent hypothermia.	• Infusion of crystalloid, colloid or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery. • Infusion of warmed fluid to rewarm patients after surgery or for hypothermia.	The Ranger Irrigation Fluid Warming System is intended to warm irrigation fluids.	Substantially Equivalent and is a subset of the predicate devices Indication for Use.

Features	Subject Device Fluido AirGuard System (FAS)	Predicate Device Belmont Rapid Infuser RI2 (K141654)	Reference Device Ranger Irrigation Fluid Warming System (K060939)	Summary
Intended Use	The Fluido® AirGuard System is for use in high blood loss surgical procedures, trauma, and any situations where replacement of warmed blood or replacement fluid is required.	The Belmont Rapid Infuser RI2 is for use in high blood loss surgical procedures, trauma, and any situations where rapid replacement of warmed blood or replacement fluid 10 - 1000 ml/min is required. It can also be used to deliver irrigation fluids at up to 1000 ml/min.	The Ranger Irrigation Fluid Warming System is intended to warm irrigation fluids.	Substantially Equivalent.
Intended User	The Fluido AirGuard System is intended to be used by trained healthcare professionals.	The Belmont Rapid Infuser RI2 is intended to be used by trained healthcare professionals.	The Ranger Irrigation Fluid Warming System is intended to be used by trained healthcare professionals.	Substantially Equivalent.
Patient Population	Adult Patients Only	Adult Patients Only	Adult and Pediatric Use	Substantially Equivalent.
Intended Use Environment	The Fluido AirGuard System is intended for general operation in a hospital or alternate care environment.	The operating environment for the Belmont Rapid Infuser RI2 is general operation in hospital or alternate care environments. The Belmont Rapid Infuser RI2 will be subject to the temperature, humidity, and pressure typical of a health care environment. Sources of shock, drop, and vibration are	Healthcare facilities.	Substantially Equivalent

Features	Subject Device Fluido AirGuard System (FAS)	Predicate Device Belmont Rapid Infuser RI2 (K141654)	Reference Device Ranger Irrigation Fluid Warming System (K060939)	Summary
		also those typically found in a health care environment.		
Principle of Operation	Non-contact dry heating	Non-contact dry heating	Contact dry heating	Substantially Equivalent
Intended Fluid(s) to be Warmed	Crystalloid, colloid, or blood product, including packed red blood cells.	Crystalloid, colloid, or blood product, including packed red blood cells.	Irrigation fluids (Not applicable to SE discussion)	Substantially Equivalent
Delivery Mechanism/Intended Route of Administration	Intravenous Delivery	Intravenous Delivery	Surgical sites (Not applicable to SE discussion)	Substantially Equivalent
Components	Control System	Control System	Control System	Substantially Equivalent.
	IV Pole	IV Pole (optional)	IV Pole	
	Single use plastic disposables	Single use plastic disposables	Single use plastic disposables	
Monitoring and alarm system?	Yes	Yes	Yes	Substantially Equivalent
Power Source	AC Power Source, sealed battery (only operates indicators and alarms for AirGuard)	AC Power Source, sealed battery (only operates as a backup battery for mobile transport of the patient)	AC Power Source, no battery used	Substantially Equivalent.
User Interface Controls	Temperature	Flow, volume, temperature	None – can view temperature, but no changing from 41°C set-point.	Substantially Equivalent. For FAS, the flow and volume control is not managed through the

Features	Subject Device Fluido AirGuard System (FAS)	Predicate Device Belmont Rapid Infuser RI2 (K141654)	Reference Device Ranger Irrigation Fluid Warming System (K060939)	Summary
			(Not applicable to SE discussion)	user interface. Instead, it is controlled by pressurizing the fluid bag and using the rolling clamp within the disposable set. The user interface, however, does display the estimated flow and volume.
User Displays	Operation codes, error codes, warning codes, and maintenance codes	Operation codes, error codes, warning codes, and maintenance codes	Error codes, warning codes	Substantially Equivalent
Maximum In-Line Pressure	300 mmHg	300 mmHg	None, no pressure system	Substantially Equivalent
Prime Volume	Standard Disposable: 90ml Trauma Set: 145 ml	100 mL	308 mL (Not applicable to SE discussion)	Substantially Equivalent,
Max Flow Rate	Standard set ≈ 400 mL per minute Trauma Set ≈ 900 mL per minute	1,000 mL per minute	867 mL per minute (Not applicable to SE discussion)	Substantially equivalent
Warmer Type	In-Line	In-Line	In-Line	Substantially Equivalent

Features	Subject Device Fluido AirGuard System (FAS)	Predicate Device Belmont Rapid Infuser RI2 (K141654)	Reference Device Ranger Irrigation Fluid Warming System (K060939)	Summary
			(Not applicable to SE discussion)	
Warming Technology	Infrared Heating	Electromagnetic Inductive Heater	Metal plate heated by electrical resistance (Not applicable to SE discussion)	Substantially equivalent. The subject device shares substantially equivalent in-line warming of blood and fluids through the use of an indirect heat source, with the Belmont Rapid Infuser RI2 predicate device.
Heating Methodology	The hardware device radiates infrared heat directly to the blood or IV fluid circulating through the single use plastic disposables.	The hardware device heats the heat exchanger, which transfers the heat to the blood or IV fluid circulating through the single use plastic disposables.	A metal plate is heated by electrical resistance, the disposable cassette contacts the plates and the fluid is warmed. (Not applicable to SE discussion)	Substantially Equivalent
Heating Control	Input/Output Infrared Temperature Sensors, controlled by software	Input/Output Infrared Sensor controlled by software	Temperature is measured by temperature sensor and controlled by software. (Not applicable to SE discussion)	Substantially Equivalent

Features	Subject Device Fluido AirGuard System (FAS)	Predicate Device Belmont Rapid Infuser RI2 (K141654)	Reference Device Ranger Irrigation Fluid Warming System (K060939)	Summary
Temperature Monitoring	The temperature sensors measure the temperature at the entrance and the exit of the cassette, located in the single use disposable component.	Infrared temperature sensors which are mounted at the entrance and the exit of the heat exchanger, monitor the temperature of fluid as it enters and exits the heat exchanger.	Sensor measures temperature before it leaves the cassette.	Substantially Equivalent.
Temperature viewing (on screen)?	Yes	Yes	Yes (Not applicable to SE discussion)	Substantially Equivalent
Occlusion Detection	No occlusion detection system	Integrated occlusion detection system	No occlusion detection system	Substantially Equivalent
Mechanism of Pressurizing Fluid	Compression of fluid bag	Roller compression of IV tubing	No pressure	Substantially Equivalent
Contains software?	Yes	Yes	Yes	Substantially Equivalent
Alarms	Audible and visual alarms	Audible and visual alarms	Audible and visual alarms	Substantially Equivalent
Protection from air embolism	Yes	Yes	No (Not applicable to SE discussion)	Substantially Equivalent
Pressure Regulator (max)	300 mmHg (+/-10%)	300 mmHg (+/-50mm Hg)	N/A – no pressure applied (Not applicable to SE discussion)	Substantially Equivalent
Maximum Heating Power (watts)	1200W	1440W	900W	Substantially Equivalent

Features	Subject Device Fluido AirGuard System (FAS)	Predicate Device Belmont Rapid Infuser RI2 (K141654)	Reference Device Ranger Irrigation Fluid Warming System (K060939)	Summary
			(Not applicable to SE discussion)	
Cardiac Floating Capability	Yes	Yes	No (Not applicable to SE discussion)	Substantially Equivalent
Sterilization Method for single use disposables	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide (Not applicable to SE discussion)	Substantially Equivalent

2. Performance Data

Nonclinical safety testing:

Nonclinical testing was conducted to support the safety and performance of the Fluido AirGuard System. This testing covered a range of subjects, including but not limited to:

1. Biocompatibility Testing per ISO 10993 and USP
    - Cytotoxicity
    - Irritation
    - Sensitization
    - Material Mediated Pyrogenicity
    - Bacterial Mediated Pyrogenicity
    - Acute Systemic Toxicity
2. Aluminum Leaching Testing on disposable sets, where aluminum levels were in accordance with the limits stated in 21 CFR 201.323
3. Transport testing per ISTA 3A
4. Sterilization validation per ISO 11135
5. EMC Testing per IEC 60601-1-2
6. UL Electrical Safety Testing per ANSI/AAMI ES60601-1
7. Cybersecurity Testing

Nonclinical performance testing:

1. Software Lifecycle Testing per IEC 62304
2. Human Factors Validation Testing, in accordance with FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices” issued February 2016 and IEC 62366
3. Hemocompatibility (hemolysis, platelet aggregation, S-protein, C-protein)
4. Non-Clinical Bench Performance Testing per ASTM F2172-02
5. Flow rate testing per ISO 8536-4

All non-clinical test results were found acceptable.

Clinical testing:

Clinical testing was unnecessary to establish substantial equivalence.

Nonclinical test comparison to predicate:

Substantial equivalence between the FAS and the Belmont Rapid Infuser RI2 was demonstrated through the following tests: warm-up time, output temperature, maximum flow speed, overtemperature alarm and alarm suppression, air removal, pressure comparison, minimum/maximum operating temperatures.

3. Conclusion

Based on the performance testing conducted according to FDA recognized standards and guidance documents, along with the comparative analysis provided in the substantial equivalence table, it can be concluded that the FAS is substantially equivalent to the Belmont Rapid Infuser RI2 cleared under K141654.