



November 18, 2025

The Surgical Company International B.V.  
Gianpaolo Soares  
RA Project Manager  
Paalbergweg 3  
Amsterdam, North Holland 1105 AG  
Netherlands

Re: K252636

Trade/Device Name: Fluido Compact System  
Regulation Number: 21 CFR 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: Class II  
Product Code: LGZ  
Dated: August 20, 2025  
Received: August 20, 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](mailto: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, Infusion Devices

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.

K252636

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Please provide the device trade name(s).

?

Fluido Compact System

Please provide your Indications for Use below.

?

The device can be used with the following products:

- Plasma
- Packed red blood cells
- Crystalloid intra venous (IV) fluids
- Synthetic Colloid intra venous (IV) fluids

The system is indicated to be used in a healthcare environment to help prevent hypothermia. The devices can be used in the full clinical environment. The Fluido Compact System can be used in adult and pediatric patients (weighing 3.5 kg or more) who require fluid warming prior to the administration of blood products or IV fluids to help prevent hypothermia. The system is intended to be used by healthcare professionals, e.g., nurses, medical specialists, and doctors.

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

Traditional 510(k) Premarket Notification  
Fluido® Compact System  
November 2025

<b>Submitter Name and Address</b>	The Surgical Company International B.V., doing business as TSC Life Paalbergweg 3 Amsterdam, 1105 AG The Netherlands
<b>Contact Person</b>	Name: Gianpaolo Soares Title: Regulatory Affairs Project Manager, TSC Life Company Telephone: +31 20 790 2100 Email: fda.tsclife-us@tsc-life.com
<b>Device Information</b>	Name of Device: Fluido® Compact System Common or Usual Name: Infusion Pump Classification Name: Infusion Pump, 21 CFR 880.5725 Regulatory Class: II Product Code: LGZ
<b>Predicate Information</b>	Name of Predicate: Fluido® Compact Blood and Fluid Warming System 510(k) Number: K211618 This predicate has not been subject to a design-related recall. No reference devices were used in this submission.
<b>Device Description</b>	<p>The Fluido Compact System is a Blood and Fluid Warming System. The system is suitable for low to moderate flow applications. For high flow applications (higher than 100 ml/min for more than 5 minutes) the use of a high flow system is recommended.</p> <p>The Fluido Compact System uses conduction heating technology to warm blood and fluids. Based on in-line sensors, the system calculates the energy required to safely warm the infusates.</p> <p>The Fluido Compact System can be used with patients who require fluid warming prior to the administration of blood products or IV fluids, to help prevent hypothermia. The system is intended to be used in a healthcare environment by healthcare professionals, e.g. nurses, medical specialists, doctors. Only medical professionals shall interact with the system. The devices must only be used on the order of a physician.</p>
<b>Indications for Use</b>	<p>The device can be used with the following products:</p> <ul style="list-style-type: none"><li>• Plasma</li><li>• Packed red blood cells</li><li>• Crystalloid intra venous (IV) fluids</li><li>• Synthetic Colloid intra venous (IV) fluids</li></ul> <p>The system is indicated to be used in a healthcare environment to help prevent hypothermia. The devices can be used in the full clinical environment. The Fluido Compact System can be used in adult and pediatric patients (weighing 3.5 kg or more) who require fluid warming prior to the administration of blood products or IV fluids to help prevent hypothermia. The system is intended to be used by healthcare professionals, e.g., nurses, medical specialists, and doctors.</p>

**Table 1: Substantial Equivalence Comparison**

	Subject Device Fluido® Compact Blood and Fluid Warming	Predicate Device Fluido® Compact Blood and Fluid Warming	Substantial Equivalence
510(k) Number	Not yet assigned	K211618	N/A
Manufacturer	The Surgical Company International B.V.	The Surgical Company International B.V.	Same
Trade name	Fluido® Compact System	Fluido® Compact Blood and Fluid Warming System	Same
CFR Regulation Number	21 CFR 880.5725	21 CFR 880.5725	Same
Product Code	LGZ	LGZ	Same
Classification	Class II	Class II	Same
Review Panel	General Hospital	General Hospital	Same
Intended Use	The Fluido Compact System can be used with patients who require fluid warming prior to the administration of blood products or IV fluids, to help prevent hypothermia. The system is intended to be used in a healthcare environment by healthcare professionals, e.g. nurses, medical specialists, doctors. Only medical professionals shall interact with the system. The devices must only be used on the order of a physician.	The Fluido® Compact System can be used with patients that need fluid warming prior to administration of blood products and IV fluids to help prevent hypothermia. The system is intended to be used in hospital by healthcare professionals, e.g., nurses, medical specialists, doctors. Only medical professionals shall interact with the system. The devices must only be used on the order of a physician.	Same, minor rewording to align intended use statement with use environment
Description of Device	The Fluido® Compact System consists of Fluido Compact Warming Module, Fluido Compact Control Module and Fluido Compact Standard Set & Fluido Compact Standard Set with Drip Chamber (disposable). The Fluido Compact system is designed to supply warm fluids at 39°C set point with flow rates from 5 to 100 ml/min. The sterile disposable set consist of a plastic housing and biocompatible coated aluminum heater plate. Heat from the warming module is transferred through the heat transfer part into the fluids that is circulating through the inner part of the cassette. The disposable is connected to the blood or fluid source (Infusate reservoir) and the patient line on the other end. The disposable has standard luer lock fittings on both ends. The Control Module serves as the power supply for the Warming module.	The Fluido® Compact System consists of Fluido Compact Warming Module, Fluido Compact Control Module and Fluido Compact Standard Set & Fluido Compact Standard Set with Drip Chamber (disposable). The Fluido Compact system is designed to supply warm fluids at 39°C set point with flow rates from 5 to 100 ml/min. The sterile disposable set consist of a plastic housing and biocompatible coated aluminum heater plate. Heat from the warming module is transferred through the heat transfer part into the fluids that is circulating through the inner part of the cassette. The disposable is connected to the blood or fluid source (Infusate reservoir) and the patient line on the other end. The disposable has standard luer	Same

	Subject Device Fluido® Compact Blood and Fluid Warming	Predicate Device Fluido® Compact Blood and Fluid Warming	Substantial Equivalence
		lock fittings on both ends. The Control Module serves as the power supply for the Warming module.	
Patient Population	Adult and Pediatric (weighing 3.5 kg or more)	Adult	Different – subject device includes pediatric indication. Human factors, performance, biocompatibility, aluminum leaching, sterilization residues, and the risk file were thoroughly evaluated to confirm that none of these factors adversely affect the device.
User	Healthcare professionals e.g., nurses, medical specialists, doctors	Healthcare professionals e.g., nurses, medical specialists, doctors	Same
Use Environment	Hospital, clinical and field environments	Hospital, clinical and field environments	Same
Operating Principle	Reusable Conduction Warmer Reusable Controller Disposable sterile	Reusable Conduction Warmer Reusable Controller Disposable sterile	Same
Prescription Use/ Over-The-Counter use	Prescription Use	Prescription Use	Same
Administered Fluids	IV Fluids, Blood Products	IV Fluids, Blood Products	Same
Fluid Path	Sterile Fluid Path	Sterile Fluid Path	Same
System Components	<ol style="list-style-type: none"> <li>1. Reusable Warmer</li> <li>2. Reusable Controller</li> <li>3. Single Use Disposable sterile set (Standard Set, Standard Set with drip chamber)</li> </ol>	<ol style="list-style-type: none"> <li>1. Reusable Warmer</li> <li>2. Reusable Controller</li> <li>3. Single Use Disposable sterile set (Standard Set, Standard Set with drip chamber)</li> </ol>	Same
Safety Features	<ul style="list-style-type: none"> <li>• Closed-loop temperature control</li> <li>• Over-temperature control and cut off (ASTM F2172-02)</li> <li>• Independent shut-off of heater and notification</li> <li>• Independent heater temperature monitoring circuit</li> </ul>	<ul style="list-style-type: none"> <li>• Closed-loop temperature control</li> <li>• Over-temperature control and cut off (ASTM F2172-02)</li> <li>• Independent shut-off of heater and notification</li> <li>• Independent heater temperature monitoring circuit</li> </ul>	Same
Warming technology	Conduction	Conduction	Same
Heat exchange	Inline disposable	Inline disposable	Same
Temperature control	Closed Loop temperature control	Closed Loop temperature control	Same
Fluid Temperature Output	39°C ± 2°C	39°C ± 2°C	Same

	Subject Device Fluido® Compact Blood and Fluid Warming	Predicate Device Fluido® Compact Blood and Fluid Warming	Substantial Equivalence
Safety cut off Temperature	49°C	49°C	Same
Flow Rate Range	Standard Set: 5 – 100 ml/min	Standard Set: 5 – 100 ml/min	Same
Storage Conditions/ Specifications	Warmer and Controller: -40°C – 50°C at 10% to 90% relative humidity  Disposable Set: -20°C – 40°C at 10% to 90% relative humidity	Warmer and Controller: -40°C – 50°C at 10% to 90% relative humidity  Disposable Set: -20°C – 40°C at 10% to 90% relative humidity	Same
Power Source	AC power supply 100-240 V ~ 50/60Hz) 1.6A	AC power supply 100-240 V ~ 50/60Hz) 1.6A	Same
Dimensions	Warmer: 16.5 cm x 7.5 cm x 5.0 cm  Controller: 28.5 cm x 12.0 cm x 19.5 cm  Disposable Set: 14.6 cm x 3.5 cm x 1.1 cm	Warmer: 16.5 cm x 7.5 cm x 5.0 cm  Controller: 28.5 cm x 12.0 cm x 19.5 cm  Disposable Set: 14.6 cm x 3.5 cm x 1.1 cm	Same
Weight	Warmer (without disposable): 450g  Controller: 1.7kg  Disposable Set: 24g (cassette)	Warmer (without disposable):  450g Controller: 1.7kg  Disposable Set: 24g (cassette)	Same
Performance	<ul style="list-style-type: none"> <li>IEC 60601-1</li> <li>IEC 60601-1-2</li> <li>Acceptable aluminum leaching levels for intended population</li> </ul>	<ul style="list-style-type: none"> <li>IEC 60601-1</li> <li>IEC 60601-1-2</li> <li>Acceptable aluminum leaching levels for intended population</li> </ul>	Same
Sterilization	Disposable Set: Ethylene oxide sterilized	Disposable Set: Ethylene oxide sterilized	Same
Biocompatibility	ISO 10993	ISO 10993	Same

**Performance Data**

- *Human factors* – Determined no impact for added pediatric patient population.
- *Performance* – Same 5–100 mL/min flow and temperature specifications. No impact for added pediatric patient population.

**Safety Data**

- *Biocompatibility* – Determined no new testing required for added pediatric patient population.
- *Aluminum leaching* – Toxicologic risk assessment shows aluminum leaching levels within safe limits for pediatric patient population  $\geq 3.5$  kg.
- *Sterilization residuals (EO/ECH)* – Toxicologic risk assessment shows EO/ECH levels within safe limits for pediatric patient population  $\geq 3.5$  kg.
- *Cybersecurity* – Data provided as required by FDA guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” issued June 27th, 2025.
- *Risk assessment* – No new risks related to added pediatric patient population identified.

**Conclusion**

The sole purpose of this Traditional 510(k) submission is to expand the indicated patient population to include pediatric patients weighing 3.5 kg or more. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Fluido® Compact System is substantially equivalent to the Fluido® Compact Blood and Fluid Warming System cleared under K211618 with respect to the indications for use, target populations, treatment method, and technological characteristics.