June 5, 2023

The Surgical Company International B.V.
Inette Nieveen
RAQA Director
Beeldschermweg 6F
Amersfoort, Utrecht 3821 AH
Netherlands

Re: K211618
Trade/Device Name: Fluido Compact Blood and Fluid Warming System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: LGZ
Dated: June 2, 2023
Received: June 2, 2023

Dear Inette Nieveen:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Digitally signed by Jake K. Lindstrom -S
Date: 2023.06.05 16:41:56 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211618

Device Name
Fluido Compact Blood and Fluid Warming System

Indications for Use *(Describe)*
The Fluido Compact Blood and Fluid Warming System can be used in adult patients that need fluid warming prior to administration of blood, blood products and IV fluids to help prevent hypothermia. The system is intended to be used 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) summary is in accordance with the requirements of 21 CFR 807.92

SUBMITTER *807.92(a)(1)*	
Submitter Name:	The Surgical Company International B.V.
Submitter Address:	Beeldschermweg 6F 3821 AH Amersfoort, The Netherlands
Phone Number:	+31 (0) 33 4507250
Contact Person:	F (Federica) Federici
Date Prepared:	October 25, 2022
DEVICE *807.92(a)(2)*	
Device Trade Name:	Fluido® Compact System
Common Name	Infusion Pump
Classification	21 CFR 880.5725
Product Code:	LGZ
Review Panel:	General Hospital
Device Class:	Class II
PREDICATE DEVICE *807.92(a)(3)*	Vital Signs, Inc. enFlow Model IV Fluid Warmer (K112902) (a GE Healthcare Company)
DEVICE DESCRIPTION *807.92(a)(4)***:** The Fluido® Compact System consists of Fluido Compact Warming Module, Fluido Compact Control Module and Fluido Compact Standard Set (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. Fluid and blood are warmed during infusion or transfusion. The delivery of heat is done by heat exchange. A warming module exchanges heat to a disposable set, which is connected to the fluid reservoir and the patient line via conduction warming technology The fluid temperature is controlled by closed loop software and guarded by sensors and has a redundant safety module for fluid overtemperature shutoff.	
INTENDED USE / INDICATION FOR USE *807.92(a)(5)***:**	The Fluido Compact System can be used in adult patients that need fluid warming prior to administration of blood, 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.

SUMMARY OF TECHNOLOGICAL CHARCHTERISTICS COMPARISON *807.92(a)(6)***:**

Fluido® Compact Blood And Fluid Warming System device has the same fundamental technological characteristics as the predicate device. Similarities and differences are listed in the table below.

Use Characteristics	Fluido® Compact Blood And Fluid Warming System	Predicate enFlow IV Fluid Warmer	Equivalence
Patient Population	Adult	Not defined	Similar
User	Healthcare professionals	Healthcare professionals	Same
Use Environment	Hospital	Hospital, clinical and field environments	Similar
Operating Principle	Reusable Warmer Reusable Controller Disposable sterile	Reusable Warmer Reusable Controller Disposable sterile	Same
Prescription Use/ Over-The-Counter use	Prescription Use	Prescription Use	Same
Technological Characteristics			Same/different technological characteristics
Administered Fluids	IV Fluids, Blood Products	IV Fluids, Blood, Blood Products	Similar
Fluid Path	Sterile Fluid Path	Sterile Fluid Path	Same
System Components	Reusable Warmer Reusable Controller Disposable sterile Set	Reusable Warmer Reusable Controller Disposable sterile Cartridge	Same
Safety Features	• Closed-loop temperature control • Over-temperature control and cut off (ASTM F2172-02) • Audible and Visual alarms Independent	• Closed-loop temperature control • Over temperature control and cut off (ASTM F2172-02) • Audible and Visual alarms	Same

	heater temperature monitoring circuit	• Independent heater temperature monitoring circuit	
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	40°C ± 2°C	Similar, within the physiological range
Safety cut off Temperature	49°C	45°C	Similar, still within the safety margins
Flow Rate Range	Standard Set: 5 – 100 ml/min	Keep Vein Open (KVO) to 200 ml/min	Similar
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	-30°C – 70°C at 10% to 90% relative humidity	Similar
Power Source	AC power supply 100-240 V ~ 50/60Hz) 1.6A	AC power supply 110-120 or 220-240 V 5A	Similar
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: 12.7 cm x 6.6 cm x 3.0 cm Controller: 23.6 cm x 16.8 cm x 3.8 cm Disposable cartridge: 11.4 cm x 3.8 cm x 1.0 cm	Similar
Weight	Warmer (without disposable): 450g Controller: 1.7kg Disposable Set: 24g	Warmer (without disposable): 279g Controller: 1.8kg Disposable Cartridge: 33g	Similar

Performance standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same
Sterilization	Disposable Set: Ethylene oxide sterilized	Disposable Cartridge: Gamma sterilized	Similar
Biocompatibility	ISO 10993	ISO 10993	Same

Non-clinical testing *807.92(b)(1):*
Performance testing according to applicable testing met all acceptance criteria.

Comparative bench performance testing:
- Temperature: PASS
- Flow rates: PASS
- Alarms: PASS
- Useability: PASS

Performance testing heater safety
- ASTM F2172-02 (Reapproved 2011): PASS

Electrical/EMC testing:
IEC 60601-1: PASS
IEC 60601-1-2: PASS

Clinical testing *807.92(b)(2)***:**
Clinical testing was not necessary to demonstrate substantial equivalence.

CONCLUSION OF SUBSTANTIAL EQUIVALENCE *807.92(b)(3)***:**
Performance testing to FDA recognized standards and FDA guidance demonstrates substantial equivalence to the predicate device. The predicate comparison table and performance testing provided in this 510(k) is sufficient to demonstrate that the Fluido® Compact Blood and Fluid Warming System is substantially equivalent to the legally marketed predicate device, Vital Signs, Inc. enFlow Model IV Fluid Warmer cleared under 510(k) K112902.