

510(k) Summary

Applicant:

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Device name:

Proprietary Name: Fluido Blood- and Fluid Warmer System
Common/Usual Name: Fluid and blood warmer
Classification Name: Nonelectromagnetic blood or plasma warming device,
21 CFR 864.9205 (a), Product Code 81KZL.

Predicates:

- Mallinckrodt Medical Alton Dean Fluid Warmer (FW-537), cleared through CBER, 510(k) number BK960075, substantial equivalence date February 28, 1997.
- Level 1 Fluid Warming System (H-1028), cleared through CBER, 510(k) number BK020043, substantial equivalence date June 16, 2003.
- Belmont Instrument Fluid Management System (FMS-2000), cleared through CDRH, 510(k) number K992472, substantial equivalence date August 24, 1999.
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Device description:

The Fluido Blood- and Fluid Warmer System consist of a unit and five dedicated disposables:

- 651115 Fluido Blood- and Fluid Warmer – Unit, 115V/60Hz
- 670200 Fluido S 200 – Standard set (Sterile)
- 670500 Fluido T 500 – Trauma set (Sterile)
- 670800 Fluido I 800 – Irrigation set (Sterile)
- 680801 Fluido P 801 – Irrigation set patient line (Sterile)
- 680802 Fluido P 802 – Drip chamber (Sterile)

The unit mainly consists of metal, electronics and a shell made of ABS. The disposables are mainly made of polycarbonate and PVC.

In the unit infrared energy is used for heating the blood or fluid inside the disposable cassette. By using infrared energy it is possible to heat the fluid directly without actually heating the disposable. Therefore the cassette is not a heat exchanger but merely a container to hold the fluid. The infrared energy passes through the container and is absorbed by the fluid, which as a consequence will heat up. The heating system uses standard halogen lamps to supply the infrared energy.

Intended use:

The Fluid Blood- and Fluid Warmer System is designed for use to warm blood and fluids before administration.

Technological characteristics:

Since the Fluid Blood- and Fluid Warmer System (651115) has features not previously combined in one device, substantial equivalence is determined against the following three predicates:

- Mallinckrodt Medical Alton Dean Fluid Warmer (FW-537), cleared through CBER, 510(k) number BK960075, substantial equivalence date February 28, 1997.
- Level 1 Fluid Warming System (H-1028), cleared through CBER, 510(k) number BK020043, substantial equivalence date June 16, 2003.
- Belmont Instrument Fluid Management System (FMS-2000), cleared through CDRH, 510(k) number K992472, substantial equivalence date August 24, 1999.

The Fluid Blood- and Fluid Warmer System, the Level 1 Fluid Warming System as well as the Belmont Instrument Fluid Management System all are capable of warming blood and fluids under high flow conditions.

The Fluid Blood- and Fluid Warmer System, the Mallinckrodt Medical Alton Dean Fluid Warmer as well as the Belmont Instrument Fluid Management System all warm blood and fluids through dry heat, thus eliminating the risk of water-borne contaminants.

Summary of the main non-clinical tests and results:

In order to verify performance of the Fluid Blood- and Fluid Warmer System in support of substantial equivalence, the following tests were conducted:

1. The ability of the system to warm cold fluids to a normothermic temperature over a specified range of fluid flow rates and operating conditions.
2. The ability of the system to detect and alarm at unsafe or ineffective operating conditions including operator errors, the failure of the system sensors, and other internal system malfunctions.
3. The ability of the system to safely warm blood through infra red energy.

The Fluid Blood- and Fluid Warmer System performed within specification in all of the above tests.

Conclusion:

The Fluid Blood- and Fluid Warmer System has the same intended use, performance and warming technology as devices currently on the market. Therefore, The Surgical Company International BV believes this proposed device does not raise any new safety or effectiveness issues.