

## 510(k) Summary

### Applicant:

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### Device name:

Proprietary Name: Fluido® Accessories to the Fluido® Blood and Fluid Warmer  
Common/Usual Name: Blood/fluid warmer  
Classification Name: Nonelectromagnetic blood or plasma warming device,  
21 CFR 864.9205 (a), Product Code: KZL.

### Predicate:

- Level 1®<sup>1</sup> H-1200 Fast Flow Fluid Warmer with Integrated Air Detector/Clamp

### Device description:

The Fluido® Accessories to the Fluido® Blood and Fluid Warmer comprise of the following devices:

- 661200 Fluido® Compressor (110-120V):
- 661300 Fluido® Pressure Chamber:
- 661400 Fluido® Air Guard (110-120V):
- 660500 Fluido® IV-Pole

### Intended use:

The Fluido® Blood and Fluid Warmer is indicated for warming of blood and fluids before administration. These Fluido® Accessories are intended to be used as accessories to the Fluido® Blood and Fluid Warmer:

- the Fluido® Compressor supplies pressurized air to the Fluido® Pressure Chamber;
- the Fluido® Pressure Chamber pressurizes IV-bags connected to the Fluido® Blood and Fluid Warmer;
- the Fluido® Air Guard detects air in the de-aeration chamber of the Fluido® disposable;
- the Fluido® IV-Pole at which all Fluido® devices can be mounted.

<sup>1</sup> Level 1® is a registered trademark of Level 1, Inc. (Smiths Medical).



**Technological characteristics:**

- the Fluido® Compressor supplies pressurized air to and is based upon the membrane pump principle;
- the Fluido® Pressure Chamber consists of a dual chamber configuration with a common pressure regulator, individual manometers and an overpressure relief valve;
- the Fluido® Air Guard detects air in the de-aeration chamber of the Fluido® disposable. As soon as the ultrasonic sensor detects the fluid level inside the de-aeration chamber to fall below a fixed level, the shut-off valve closes the supply tubing, thus preventing air being supplied to the patient;
- the Fluido® IV-Pole has an integrated air tubing between the Fluido® Compressor and Fluido® Pressure Chamber.

These devices mainly consist of metal, electronics and ABS.

**Summary of the main non-clinical tests and results:**

In order to verify performance of the Fluido® Accessories (in combination with the Fluido® Blood and Fluid Warmer) the following tests were conducted:

- Fluido® Compressor: pressure and flow;
- Fluido® Pressure Chamber: pressurization, air leakage, over-pressure relief valve;
- Fluido® Air Guard: air detection, foam detection, tube sensor, shut-off valve;
- Fluido® IV-Pole: stability

It was demonstrated that all devices are in compliance with the performance specifications.

**Conclusion:**

The Fluido® Accessories (in combination with the Fluido® Blood and Fluid Warmer) have the same intended use and performance as the predicate device. Therefore, The Surgical Company International BV believes these proposed devices do not raise any new safety or effectiveness issues.