

Traditional 510(k) Premarket Notification  
Level 1® Fluid Warming System H-1028  
October 8, 2002

BK070043

Level 1, Inc.  
160 Weymouth Street  
Rockland, MA 02370

**ATTACHMENT 4**

**Premarket Notification  
510(k) Summary**



**Level 1, Inc.**  
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Rockland, MA 02370 USA  
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**STATEMENT OF INTENDED USE:**

The **Level 1 Fluid Warming System (H-1028)** is for use in high blood loss surgical procedures, trauma and where rapid replacement of warmed blood or fluids is required.

**SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:**

The proposed device is *substantially equivalent* to the **Belmont Instrument Fluid Management System FMS2000**, which was the subject of Premarket Notification **K972284**, substantial equivalence date November 13, 1997. Both the **Level 1 Fluid Warming System H-1028** and the **Belmont Instrument Fluid Management System FMS2000** warm fluids for rapid volume replacement for use in high blood loss surgical procedures, trauma, and hypothermia, while maintaining infusate at physiological temperature. Both systems are designed for use with blood products.

**PERFORMANCE DATA:**

The proposed device is *substantially equivalent* to the **Belmont Instrument Corporation FMS2000** in terms of performance characteristics tested.

**SUMMARY OF NONCLINICAL TESTS AND RESULTS:**

In order to verify performance of the **Level 1 Fluid Warming System H-1028** in support of substantial equivalence, the following tests were conducted:

1. The ability of the system to warm cold fluids to a physiological 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.

The **Level 1 Fluid Warming System H-1028** performed within specification in all of the above tests.

**CLINICAL STUDIES:**

Clinical Studies were not deemed necessary regarding the use of the **Level 1 Fluid Warming System H-1028** and the disposable accessories that are to be used with the system.

**CONCLUSION:**

The **Level 1 Fluid Warming System H-1028** has the **same basic technological characteristics** and the **same intended use** as devices currently on the market. Therefore, because of the similarities to the predicate **Belmont Fluid Warming System FMS2000** device, Level 1 believes this proposed device does not raise any new safety or effectiveness issues.



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