

Section Six
510(K) Summary

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Date : September 27, 1995.
 Submitter : Biegler Medical Products Inc.
 Contact : Martin Costello
 Trade Name : Biegler BW385L Blood & Infusion Warmer
 Common Name : Infusion and/or Blood Warmer
 Classification Name : Warmer [Classification Names for Medical Devices
 & In Vitro Medical Diagnostic Products]

The Biegler BW385L Blood & Infusion Warmer is designed to reduce complications associated with the infusion of blood and other liquids that are cooler than normal body temperature. The BW385L warms the fluid by means of a metal Heat Exchanger which is adjacent to an I.V. Tubing Extension Set through which the fluid to be heated flows. The cylindrical Heat Exchanger has a series of grooves; the Extension Set tubing is 'wrapped' around the Exchanger and into these grooves. The BW385L operates on a 120 volt (or where required 220 Volt) A.C. power source and is controlled by an on-off switch on the plastic face of the instrument. Above the on-off switch is an LED temperature monitor. The BW385L Blood & Infusion Warmer weighs 2.5 Kg. and is equipped with a dual knob clamp at the back of the instrument for I.V. pole attachment. The infusate is warmed to approximate body temperature as it travels a path around the constantly monitored and regulated Heat Exchanger. The BW385L is UL / C-UL approved and units placed to date have received special CSA inspection certification.

The Biegler BW385L Blood and Infusion Warmer has the same intended use as several devices now marketed in the U.S. The DW1000, Baxter; the Hotline^{R1}, Level 1; the FloTem^{R2}, DataChem and the Fenwal^{R3}, Baxter are all used to heat infusate. The Hotline uses a fluid heat exchange system while the others utilize 'dry-wall' Heat Exchangers. The DW1000 has a cylindrical, metal, heated Exchanger over which a plastic cuff is fixed. The infusate is heated as it flows through this cuff. The Fenwal envelopes the infusate 'bag' between heated, metal exchanger plates. The FloTem Heat Exchanger is channelled allowing I.V. tubing to be fitted into the grooves. The four aforementioned warmers operate by means of heating elements that range from 300 to 360 Watts. These units provide sufficient heat for the fluid to approximate normal body temperature distal to the warmers.

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^{R1}HOTLINE is Registered Trademark of Level 1 Technologies

^{R2}FloTem is a Registered Trademark of DataChem

^{R3}Fenwal is a Registered Trademark of Baxter Health Care

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The BW385L by comparison has a dry-wall channelled Heat Exchanger heated by a 400 Watt element. Data compiled by Biegler G.m.b.H. using the BW385L Blood & Infusion Warmer with Biegler Extension Sets, ambient temperature of 21 oC., with liquids at initial temperatures of both 18 oC. and 07 oC. indicate that at moderate infusion rates (to 6 litres / hour) the BW385L adds sufficient heat to the liquid medium to claim substantial equivalence to the warmers mentioned above.