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SAFETY & EFFECTIVENESS SUMMARY

The IMED GEMINI PC-1TX Volumetric Infusion Pump/Controller is a single channel linear peristaltic infusion device. PC-1TX incorporates the same general safety features exhibited in the Models PC-1, PC-2, PC-2TX, and PC-4. The Gemini family of infusion devices are intended for intravascular administration of fluids, medications, blood, and blood products into a patient in a controlled manner. The PC-1TX has been designed as a fail-safe device which utilizes state-of-the-art microprocessor circuitry to monitor the operation of the device and to alarm visually and/or audibly whenever assigned parameters have been exceeded, resulting in shutdown until corrective actions, as indicated, have been completed by the user. The PC-1TX displays information relative to operations including advisories, prompts, alarms, and malfunctions. A full description of each of these types of information is provided in the proposed Operator's Manual (see Labeling Section of this Submission).

The PC-1TX is designed to operate functionally in the same manner as the PC-1, PC-2TX, and PC-4 with the same level of accuracy, $\pm 5\%$. The PC-1TX design will be reviewed by Underwriter's Laboratories and the Canadian Standards Association for independent assurance of conformance to electrical safety standards.

I hereby certify that, in my capacity as a Compliance Engineer of IMED's Regulatory Affairs Department, I believe that, to the best of my knowledge, all data and information submitted in this Premarket Notification are truthful and accurate and that no material fact has been omitted.

Signature

Dale Coleman

Name

2 February 1996

Date

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501(k) Number