IMED Corporation

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SAFETY AND EFFECTIVENESS SUMMARY

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1.0 SUBMITTER INFORMATION

IMED Corporation
9775 Businesspark Ave.
San Diego, CA 92131-1699

Contact Person: Ahmad Sajadi, Manager, Regulatory Affairs

2.0 DEVICE NAME

Trade Name:	The IMED Ambulatory Infusion Pump and Administration Sets
Common Names:	Infusion Pump Intravascular Administration Sets
Classification Names:	Infusion Pumps (21 CFR 880.5725), Class II IV Administration Sets (21 CFR 880.5440), Class II

3.0 PREDICATE DEVICE

The IMED Ambulatory Infusion Pump is substantially equivalent to the CADD series of ambulatory infusion pumps (CADD-PCA®, CADD-TPN™, and CADD-PLUS®). These devices are currently being marketed by Pharmacia Deltec (St. Paul, MN). Some features of the IMED Ambulatory Infusion Pump are equivalent to the Gemini PC-2TX Infusion Pump/Controller. The IMED Ambulatory Administration Sets are substantially equivalent to the Gemini series of IV Administration Sets. The Gemini devices have been reviewed by FDA and are currently being marketed by IMED Corporation (San Diego, CA).

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4.0 DESCRIPTION OF THE SUBJECT DEVICE

The IMED Ambulatory Infusion System is comprised of a cassette assembly and the pump. The system uses a rotary peristaltic pumping action which physically pumps fluid to the patient when used in conjunction with the dedicated administration sets. Various configurations of the IV administration sets are available.
The IMED Ambulatory Infusion System incorporate the following features:

- ★ Battery status Indicator; provides estimated remaining battery run time.
- ★ Ease of Use; provides operator queries, visual and audio alarms.
- ★ Flow Rates; range of 0.1-999 mL/hr
- ★ Free Flow Protection; administration set-based protection.
- ★ Occlusion Pressure; provides multiple detection options.
- ★ Secondary Infusion; provides dual rate sequential piggyback infusions.
- ★ Tamper-resistant Mode; provides the ability to lockout keypad.
- ★ Volume-To Be-Infused; range of 0.1-9999 mL.

5.0 INTENDED USE OF THE SUBJECT DEVICE

The IMED Ambulatory Infusion System is intended for use in a health care facility as well as home health care setting to pump standard IV fluids, medications, blood and blood products into a patient in a controlled manner. The system is electrically powered, with back up battery power available, and uses rotary peristaltic pumping action to infuse fluids. The IMED Ambulatory Infusion System is capable of detecting air-in-line and occlusions.

6.0 TECHNOLOGICAL ASPECTS OF THE SUBJECT DEVICE

The technological aspects of the IMED Ambulatory Infusion Pump and Administration Sets are substantially equivalent to the technological aspects of the CADD series of infusion pumps and IMED Gemini Administration Sets. This is supported by the comparison of the design and component materials of both systems. The performance data resulting from the comparative functional testing also support the substantial equivalence claim to the predicate device. The IMED Ambulatory System complies with the applicable safety and/or performance standards.

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TECHNOLOGICAL ASPECTS (CONT'D)

The IMED Ambulatory Administration Sets are equivalent to the Gemini Administration Sets. The materials are equivalent in that per the device category definition in the Tripartite Biocompatibility Guidance For Medical Devices and ISO 10993; Biological Testing of Medical and Dental Materials and Devices, Part 1, Guidance on Selection of Tests (as modified by FDA effective 1 July 1995), both are "Externally Communicating Devices for Blood Path Indirect and Short-term Contact Duration." Consequently all materials must meet the same testing criteria as outlined in the above referenced documents. Biocompatibility data to support this claim is provided.

The conclusion drawn from the Performance Data demonstrates that the IMED Ambulatory Infusion Pump and Administration Sets are equivalent to legally marketed devices and that they perform as well as or better than the predicate devices.

7.0 CERTIFICATION

I hereby certify that to the best of my knowledge all information contained in this Premarket Notification is truthful and accurate and that no material fact has been omitted.

Ahmad Sajadi Date: August 15, 1995

Ahmad Sajadi
Manager, Regulatory Affairs