K950419

SAFETY AND EFFECTIVENESS SUMMARY

1.0 SUBMITTER INFORMATION

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

JUN 2 [illegible]

Contact Person: Ahmad Sajadi, Manager, Regulatory Affairs

2.0 DEVICE NAME

Trade Name: Orion™ 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 Orion Infusion Pump and Administration Sets are substantially equivalent to the IMED Gemini PC-2TX Infusion Pump and Administration Sets. The Gemini devices have been reviewed by FDA and are currently being marketed by IMED Corporation.

4.0 DESCRIPTION OF THE SUBJECT DEVICE

The Orion Infusion System is a modular system that will allow the user to assemble infusion systems which meet a wide range of patient needs. The electromechanical portion of the system is assembled from three building blocks. Two of these blocks are interchangeable Interface Units. The third is a pump module, which physically pumps fluid to the patient when used in conjunction with the dedicated administration sets. One through four pump modules can be assembled/connected to each Interface Unit. Various configurations of the IV administration sets are available. The Orion Infusion System consists of the following components:

- Advanced Interface Unit
- Basic Interface Unit
- Large Volume Parenteral Pump Unit
- IV Administration Sets

INTENDED USE OF THE SUBJECT DEVICE

The Orion™ Infusion System is intended for use in a health care facility to pump standard IV fluids, medications, whole blood and packed red blood cells into a patient in a controlled manner. The system is electrically powered, with back up battery power available, and uses linear peristaltic pumping action to infuse fluids. The Orion System is capable of detecting air-in-line and occlusions. The Orion System is also indicated for Epidural infusions. Appropriate warnings and precautions to safely and accurately infuse Epidural are provided in the product labeling.

TECHNOLOGICAL ASPECTS OF THE SUBJECT DEVICE

The technological aspects of the subject devices are substantially equivalent to the technological aspects of the IMED Gemini PC-2TX Infusion Pump and 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 Orion System complies with the applicable safety and/or performance standards.

The Orion System contains the following additional features:

- Drug Name Display
- Multichannel Coordinated Infusion
- Battery Run Time Indicator
- PC Card Capability

The Orion 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 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 Tripartite Guidance document. Biocompatibility data to support this claim is provided.

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

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: 1/27/95

Ahmad Sajadi
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 1995

Mr. Amhad Sajadi
Manager, Regulatory Affairs
IMED Corporation
9775 Businesspark Avenue
San Diego, California 92131-1699

Re: K950419
Trade Name: The IMED Orion Infusion Pump and Administration Sets
Regulatory Class: II
Product Code: FRN, FPA
Dated: May 9, 1995
Received: May 10, 1995

Dear Mr. Sajadi:

We have reviewed your Section 510(k) notification of intent to market the device reference above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulation.

In addition, on August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them.

The specific requirement of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Timothy A. Ulatowski
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures