

ICU Medical Inc.
Intravascular Administration Set

APR -2 1997

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14. Appendix F. 510(k) Summary of Safety and Effectiveness

**The following section is included as required by
the Safe Medical Device Act (SMDA) of 1990.**

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K964435

Applicant Information:

Date Prepared: May 29, 1996
Name: ICU Medical Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Richard Waters
Phone Number: (714) 366-4390
Fax Number: (714) 366-8368

Device Information:

Trade Name: Intravascular Administration Set
Common Name: IV Set
Classification Name: Intravascular Administration Set

Equivalent Devices:

Medical Product Specialists I.V./Secondary Sets
McGaw Intravenous Administration Sets
Churchill Medical Systems IV/Extension Sets

Device Description:

The Intravascular Administration Set is a single use, sterile, non-pyrogenic device which provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein). Each set will be manufactured to unique specifications using dimensions, components and configurations specified by the customer. Standard sets will also be offered. Components used in the IV sets may be either manufactured by ICU Medical or purchased from other manufacturers. Components will be assembled into configurations specified by the customer and packaged.

Intended Use:

The Intravascular Administration Set is a single use, sterile, non-pyrogenic device which provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein).

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Comparison To Predicate Device:

| Characteristic Compared | ICU MEDICAL INTRAVASCULAR ADMINISTRATION SET | PREDICATE INTRAVASCULAR ADMINISTRATION SET |
|--------------------------------|---|---|
| Product Labeling | Single Use, Non-pyrogenic, Sterile fluid pathway in un-opened, undamaged package. Directions for use on labeling | Single Use, Non-pyrogenic, Sterile fluid pathway in un-opened, undamaged package. Directions for use on labeling |
| Intended Use | Single use, Sterile, non-pyrogenic device which provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein). | Single use, Sterile, non-pyrogenic device which provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein). |
| Design | Tubing of various lengths and inside diameters are configured with some or all of the following: spike/drip chambers (as part of a set only), clamps, injection site(s), filters, backcheck valves and male luer fitments. Packaged in medical grade fiber-free peelable paper lidding and pouching material. | Tubing of various lengths and inside diameters are configured with some or all of the following: spike/drip chambers, clamps, injection site(s), filters, backcheck valves and male luer fitments, huber needle. Packaged in medical grade fiber-free peelable paper lidding and pouching material. |