

K955821 JUL 10 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

RE: 510(k) NOTIFICATION
Intravascular Administration Set

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

The I.V. Administration Sets of this Notification provide a means for administering Parenteral solutions from a standard solution container intravenously to a patient. The sets include a rigid plastic spike or other means for attachment to a solution source, a length of PVC tubing, a clamp for controlling solution flows through the tubing and a male luer lock connector. Some configurations of the sets include needleless injection sites, check valves and air-venting filters. Various configurations are substantially equivalent to pre-amendment devices or to devices found substantially equivalent to prior devices in 510(k) Nos. K944320 and/or K860605. Components of the sets are made of the same materials usually used by previously-marketed sets and both packaging and sterilization procedures are consistent with those generally used in the medical device industry.

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