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510(k) SUMMARY

Submitter's Name: Invacare Infusion Systems
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Name of Device: Model D-290P Administration Set with Check Valve

Legally Marketed Device to Which Substantial Equivalency Is Claimed:

Block Medical, Inc. Model V021014 and IVAC Model 59093 Administration Sets with Check Valve.

Description of Device:

The Model D-290P is an administration set that incorporates standard, off-the-shelf, I.V. set components (including a check valve), Medical Grade PVC tubing and a non-fluid path pumping cartridge.

Intended Use:

The Model D-290P Check Valve administration set is targeted for use with those applications where a piggyback infusion is specified. The Model D-290P set is used in conjunction with a commercially available secondary infusion line inserted in the upper Y-Site and with the Invacare Model 1200 pump.

Technological Characteristics:

The Invacare Infusion Systems, Block Medical, Inc. and IVAC administration sets with check valves have the same general design and incorporate similar technologies, materials, and components.

The primary function of the Invacare, Block and IVAC check valve sets is to administer fluids initially from a primary container until empty and then from a secondary container to a patient's vascular system. The technological characteristics of the devices are the

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same and raise no new questions of safety and effectiveness. Invacare concludes that the Model D-290P is substantially equivalent to the Block Model V011014 and IVAC Model 59093 in providing primary and secondary infusion therapy that require the use of administration sets with a check valve.

Nonclinical Tests and Results

No changes in the Invacare Infusion Systems Model 1200 Infusion Pump were necessary to add the Model D-290 administration set.

Nonclinical tests were deemed not necessary to support the claim of substantial equivalence to the Block Medical and IVAC administration sets.

A certificate of compliance for USP Biological Tests has been furnished by Medex, the check valve supplier, for their check valve that is being used in the Model D-290P administration set.