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K963012

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510(k) SUMMARY (21CFR Subpart 807.92)

(a) (1) Submitter Identification:

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- (a)(2) Device Name: Bioject Needle-Free Vial Adapter (13 mm)
Common Name: Needle-Free Fluid Transfer Device
Classification Name: Accessory to a syringe, 21 CFR 880.5860

- (a)(3) Predicate Devices: Baxter Needle*Less™ Drug Vial Adapter (K894177)
Abbott LifeShield™ Vial Adapter (K920737)

(a)(4) Device Description: The Bioject Needle-Free Vial Adapter is a device which provides single access to 13 mm drug vials for withdrawal of medications, withdrawal and transfer of diluents, reconstitution and withdrawal of medications, without the use of needles. The Bioject Needle-Free Vial Adapter is a one piece, polycarbonate adapter with a standard female luer lock fitting compatible with standard luer taper syringes and a shielded spike designed to fit 13 mm outside diameter vial stopper overseals. The spike is designed to direct fluid along the drug vial walls in order to minimize foaming when used to reconstitute medications. The Bioject Needle-Free Vial Adapters are sterile, non-pyrogenic, and intended for single-use only. The adapters are individually packaged in a sterile, single-use Tyvek blister pack.

(a)(5) Intended Use / Indications For Use: The intended use of the Bioject Needle-Free Vial Adapter is to allow single access to 13 mm drug vials for withdrawal of medications, withdrawal and transfer of diluents, and reconstitution and withdrawal of medications, without the use of needles. The Bioject Needle-Free Vial Adapter may be used by physicians, nurses, and other practitioners who routinely administer injections, or by patients and other individuals authorized by their physicians to administer injections of prescribed medication.

(a)(6) Substantial Equivalence:, The Bioject Needle-Free Vial Adapter which is the subject of this submission is substantially equivalent to the predicate Baxter Needle*Less™ Drug Vial Adapter, K894177, and predicate Abbott LifeShield™ Vial Adapter, K920737, with respect to intended use, material, design and operational principles.

The intended use of the Bioject Needle-Free Vial Adapter is for withdrawal of medications, withdrawal and transfer of diluents, and reconstitution and withdrawal of medications, without the use of needles.

Predicate Baxter Needle*Less™ Drug Vial Adapters (K894177) and LifeShield™ Vial Adapters (K9200737) may be used to allow drug vial access for fluid (medication) transfer, and reconstitution and dilution of medications.

The Bioject Needle-Free Vial Adapter has a standard female luer lock fitting compatible with standard luer taper syringes and a shielded spike end designed to fit 13 mm outside diameter vial stopper overseals. The spike is designed to direct fluid along the drug vial walls in order to minimize foaming when used to reconstitute medications.

Both predicate vial adapters have a shielded spike end to fit the vial stopper overseals. They differ at the opposite ends which have a septum or slit reseal stopper for use with other blunt cannula devices.

Bioject Needle-Free Vial Adapters are provided sterile, nonpyrogenic, and for single-use only.

The predicate devices are provided sterile, nonpyrogenic, and for single-use only.

Product design and materials for the Bioject Needle-Free Vial Adapter demonstrate functional equivalence to the predicate devices. The device is as safe and effective as the legally marketed, predicate devices, and does not raise questions of safety and efficacy different than that of the predicate.