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SUMMARY
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Submitter's Name

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Device Name

Classification Name:	Injector & Syringe, Angiographic
Common/Usual Name:	Disposable Syringe
Proprietary Name:	Medrad Disposable Syringe

Predicate Devices

See attached reference list, Addendum 1.

Device Description

The Device is an assembly consisting of a plastic barrel, a plastic plunger, a synthetic rubber cover, and an elastomeric seal. Fluid is drawn into or expelled from the syringe by its piston which is powered and controlled by an automatic injector head. See drawing and labeling, Addendum 2.

The Device is designed to contain and hold contrast media and assist in delivery of same, to effect computerized tomography and magnetic resonance imaging, as well as, angiographic diagnostics.

The product is to be packaged in a white opaque vacuum formed plastic tray, heat sealed to a Tyvek lid. The entire package is compatible with an EtO Sterilization Cycle. See Addendum 3.

Intended Use

The intended use of the proposed device(s) duplicates the predicate device(s), in that, the proposed synthetic rubber cover, a component of the disposable syringe(s) device is used with a powered injector to assist the hospital clinician in the intravascular delivery of contrast media and flushing solutions at controlled flow rates and volumes, to effect computerized tomography, magnetic resonance, and angiographic diagnostic imaging.

Technological Characteristics

Comparisons/Distinctions:

See comparison chart, Addendum 4.

Performance Data:

See laboratory and design verification data, Addendum 5.

This substantially equivalent device excludes latex as an element of its formulation. However, there is no change in the function of the device(s), no changes in the safety or efficacy of the device(s), and the intended use remains the same.