

SUMMARY OF SAFETY AND EFFECTIVENESS DATA**1.0 B-D Contact Person**

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2.0 Device Name

Becton Dickinson Single Use Hypodermic Syringes

3.0 Predicate Device

Becton Dickinson Single Use Hypodermic Syringes

4.0 Product Description/Function**4.1 Description**

Single use sterile and non-sterile disposable hypodermic syringes manufactured by Becton Dickinson.

4.2 Function

The Becton Dickinson hypodermic syringe product line consists of single use disposable syringes intended for dispensing/administering fluids, and collection/sampling of fluids in medical practice. Their function is mechanical.

5.0 Comparison of Modified and Predicate Devices**5.1 Design Changes**

No design changes are being made

5.2 **Material Changes**

Becton Dickinson intends to change the medical grade rubber formulation used for its molded syringe plunger tip.

Becton Dickinson manufactures its predicate plunger tip using dry gum natural rubber from the Hevae Braziliensis tree. While this material has proven safe through a long history of use, its composition suggests the possibility of natural rubber allergic reactions in susceptible patients.

The proposed plunger tip contains polybutadiene synthetic rubber only. No natural rubber or other naturally occurring protein containing material is used in its formulation.

5.3 **Manufacturing Process Changes**

No manufacturing process changes are being made.

5.4 **Manufacturing Site Changes**

No manufacturing site changes are being made.

5.5 **Packaging Component Changes**

No packaging components are being changed.

6.0 **Equivalence**

The following data demonstrates functional equivalence to Becton Dickinson's predicate plunger tip and fitness for use

6.1 **Design Change**

No design changes are being made

6.2 **Material Change**

The new synthetic "latex/natural rubber free" syringe plunger tip formulation, used syringes made from this material, have been proven equivalent to existing product in functional performance (efficacy). Biological safety has been proven through a series of chemical and biological assays.

6.2.1 **Mechanical Function/Efficacy**

Syringes manufactured using the new synthetic “latex/natural rubber free” stopper material have demonstrated equivalence to syringes manufactured with natural rubber stoppers for:

- Ability to maintain a leak-proof seal.
- Perform after exposure to all expected sterilization conditions syringes will experience. This includes radiation, ethylene oxide, and autoclave methods.
- Exhibit actuation forces equivalent to current natural rubber containing syringes.
- Meet the stringent requirements for use in syringe pump application including low flow rate (0.01 ml/hr) neonatal administration of fast acting drugs.

6.2.2 **Safety**

- **Functional Safety** - Hypodermic syringes can be used in syringe pumps. Post market surveillance has identified the use of syringes in syringe pumps for administration of dopamine to neonates at low flow rates (0.1 ml/hr to 1.0 ml/hr) as the most stringent requirement. At the resultant rates of translation, the consistency of forces of movement are critical. Inconsistency in movement of the plunger and slow start-up/alarm response is undesirable.

Becton Dickinson’s predicate device meets the stringent neonatal pump application functional requirements. The proposed synthetic “latex/natural rubber free” plunger tip also meets this requirement as demonstrated in syringe pump application testing covering the range of use including low flow rate use.

- **Biocompatibility** - Syringes manufactured using the proposed synthetic “latex/natural rubber free” plunger tip have proven to be safe over specified manufacturing process and formulation variables. They pass all biological and chemical evaluations recommended in the ISO biocompatibility guidance.
- **Functional Safety** - Syringes manufactured using the proposed synthetic “latex/natural rubber free” plunger tip have proven to be functionally safe. They demonstrate functional equivalence to the predicate device in all applications, including neonatal syringe pump use

6 **Manufacturing Process Changes**

No manufacturing process changes are being made.

6 **Manufacturing Site Changes**

40 manufacturing site changes are being made.

6 **Packaging Component Changes**

No packaging components are being changed.