

SUMMARY

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Submitter's Name: IntegriTech, Inc.
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Date of Preparation: June 24, 1996

Device Name:

Proprietary Name: Safety Injection System
Common Name: Dental Aspirating Antistick Syringe
Classification Name: Cartridge Syringe

Equivalent Device: Astra Aspirating Syringe
510K Number - K85-1903
Astra Pharmaceutical Products, Inc.
50 Otis Street
Westborough, MA 01581
Phone: (508) 366-1100
UltraSafe Aspirating Syringe

Device Description: The IntegriTech Safety Injection System is a plated brass syringe with a threaded male on the end of the syringe barrel to which the metal or plastic hub of the injection needle is threaded. The barrel accommodates a 1.8 cc anesthetic carpule. The syringe has a plunger with a harpoon on one end which engages the rubber piston of the anesthetic carpule to allow aspiration of fluid during the injection to determine if the needle has entered a blood vessel. These characteristics are the same for the "Astra" syringe (K85-1903) to which we are claiming equivalence. In addition, the Safety Injection System includes a polycarbonate protective cover which in the extended position locks and completely covers the uncapped needle. This allows the syringe to be set aside during the procedure with the contaminated needle covered thereby protecting the operator, auxiliary and patient from a needlestick injury. The protective cover in the extended locked position also allows for the safe placement of the needle cap into the end of the cover which can then be retracted. This action simultaneously recaps the needle thus preventing a needlestick injury during the recapping process. The protective cover is equivalent to the polycarbonate cover on the disposable UltraSafe Aspirating Syringe by Safety Syringes, Inc. (510K #K944425, January 26, 1995). The difference is that the protective cover on the Safety Injection System (IntegriTech) is a solid autoclavable polycarbonate tube attached to an autoclavable chrome plated brass syringe barrel. This cover can be replaced as needed.