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Section 5. 510(k) Summary

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IDENTIFICATION OF THE DEVICE:

Common Name: Piston Syringe
Trade Name or Proprietary Name: Duploject, Duo Set and Duo Set A
Classification Panel: 80 General Hospital
Regulation Number: 21 CFR 880.5860
Classification: Piston Syringe
Class: Class II
Product Code: FMF

PREDICATE DEVICES:

Table 1. Primary Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Duploject	Baxter Healthcare Corporation	K973510	December 08, 1997

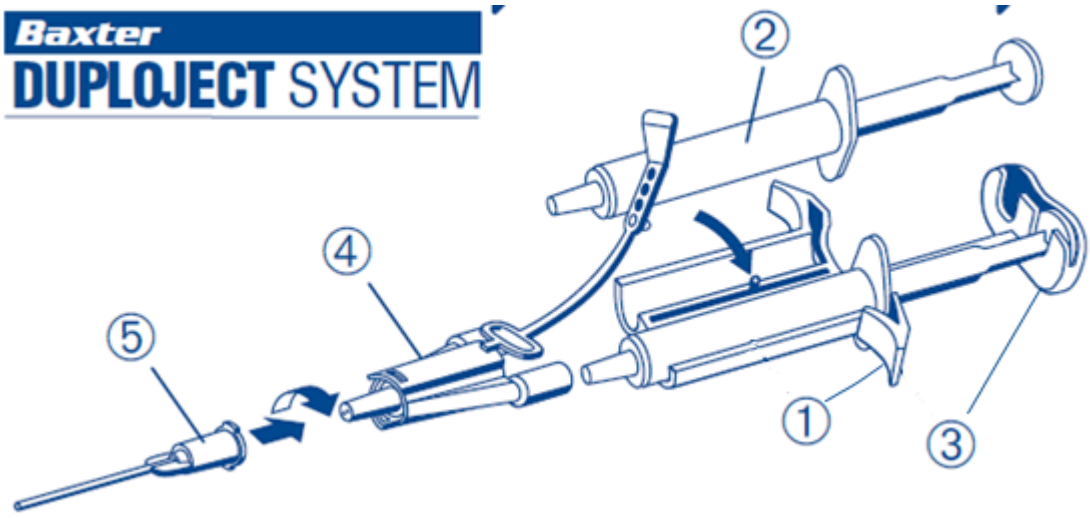
DESCRIPTION OF THE DEVICE:

Duploject

Duploject System Figure 1 consists of two identical syringes ②, each with a moveable plunger, which are snapped into a holder ① (also called Duploject clip) along their barrels and plungers. The holder has a common plunger ③ which allows simultaneous dispensing from the syringes. There is a male connector at the end of each syringe barrel to which a joining piece ④ (also called Y-piece), with a tether strap, is attached. The product applicator tip (shown is the plastic application cannula)⑤ is equipped with a Luer-piece at one end that is attached to the joining piece via a Luer-lock mechanism.

Duploject has been marketed as a kit for product reconstitution and application. Duploject has been marketed with Baxter product application devices, in the US, since 1997.

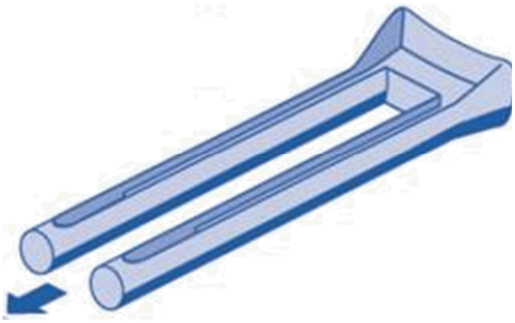
Figure 1. Duploject System



Duo Set and Duo Set A (Product Application Tips):

Baxter includes the same joining piece ④ and application cannula⑤, and a similar common plunger ③ in the packaging for frozen (versus lyophilized) Tisseel and Artiss fibrin sealants. This plunger, which is shown in Figure 2, with joining piece and application cannula is named Duo Set (when packaged with frozen Tisseel) and Duo Set A (when packaged with frozen Artiss). Use of Duo Set and Duo Set A is described in the Package Insert of the biologic, frozen Tisseel or frozen Artiss, covered in their respective BLAs. However, we wanted to mention and show the modified plunger used with the frozen fibrin sealants.

Figure 2. Duo Set/Duo Set A Plunger



Duplocath (Product Application Tips)

Product application tips, including the application cannulas, are detachable accessories of various dimensions that attach either to the Duploject syringe Luers or to the outlet of the joining piece to apply product onto a surgical site. Duplocath is an example. The application devices are selected and utilized by surgeons according to the anatomy they need to reach for delivery of fluids or solutions. Duplocath application catheters have been US marketed accessories for use with Duploject since 1998. They are accessories to the Duploject and Duo Set Systems.

Some of the product application tips for use with Duploject are designed to include a joining piece as an integral part of the device (refer to Figure 1 items ④ and⑤). Others are designed to connect to the male Luer lock outlet of the joining piece via a female Luer lock. Referring back to Figure 1, product application tips connect to Duploject as represented in ④and⑤.

INDICATIONS FOR USE:

Duploject: For the preparation and application of Tisseel Fibrin Sealant kit.

Duo Set: For the application of Tisseel Fibrin Sealant.

Duo Set A: For the application of Artiss Fibrin Sealant.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed devices have similar technological characteristics as the predicate devices. The intended use, design and function of the proposed devices are equivalent to the predicate devices.

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DEVICE COMPARISON TABLE:

Table 2 is a device comparison table outlining the differences between the predicate device and the proposed devices.

Table 2. Device Comparison Table (Predicate vs. Proposed Devices)

Features	Duploject (Predicate) (K973510)	Proposed Devices
FDA product code	FMF	Same
Indications for Use	Intended for use in the simultaneous delivery of two non-homogenous fluids or solutions onto a surgical site.	Duploject: For the preparation and application of Tisseel Fibrin Sealant kit. Duo Set: For the application of **Tisseel** Fibrin Sealant. Duo Set A: For the application of **Artiss** Fibrin Sealant.
Sterilization Method	Ethylene Oxide	Duploject: Same Duo Set/Duo Set A: Gamma
Packaging	130 µm thermoforming film	125 µm thermoforming film
Compatible Accessories*	N/A	Duploject: Duplocath device Duo Set/Duo Set A: Duplocath device
Syringe Compatibility	Compatible with 2 mL syringe	Duploject: Compatible with 3 mL syringe. No impact to fibrin sealant volume delivered to patient. Duo Set/Duo Set A: N/A
Non-Pyrogenic	Yes	Duploject: Same Duo Set/ Duo Set A: Same
Single Use	Yes	Duploject: Same Duo Set/ Duo Set A: Same
Class/Code/Regulation	Class II/80 FMF/21 CFR 880.5860	Duploject: Same Duo Set/ Duo Set A: Same

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Table 2. Device Comparison Table (Predicate vs. Proposed Devices)

Features	Duploject (Predicate) (K973510)	Proposed Devices
Materials		
Syringe Holder (Clip)	Polypropylene	Duploject: Same Duo Set/ Duo Set A: Same
Y-pieces	Polypropylene	Duploject: Same Duo Set/ Duo Set A: Same
Disposable Syringes	Polypropylene (Barrel and Plunger)	Duploject: Same Duo Set/Duo Set A: N/A
	Silicon rubber (Plunger seal)	Duploject: Polyisoprene rubber Duo Set/Duo Set A: N/A
Reconstitution Needles	Stainless Steel	Duploject: Same Duo Set/Duo Set A: N/A
Application Cannulas	Stainless Steel	Duploject: Polypropylene Duo Set/Duo Set A: Polypropylene
Components		
Integrated Syringe Holder/Plunger	1.8 mm length holder pin	Duploject: 2.4 mm length holder pin and minor dimensional changes to accommodate potential next generation products. Duo Set/Duo Set A: No
Syringe Plunger	No	Duploject: No, the plunger is integrated with the syringe holder (above) Duo Set: Yes (Color Red) Duo Set A: Yes (Color Blue)
Y-piece with tether strap	Non-pin design configuration	Duploject: Pin design configuration Duo Set/Duo Set A: Pin design configuration
Disposable Syringes	Yes	Duploject: Same Duo Set/Duo Set A: No

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Table 2. Device Comparison Table (Predicate vs. Proposed Devices)

Features	Duploject (Predicate) (K973510)	Proposed Devices
Reconstitution needles	Yes	Duploject: Same Duo Set/Duo Set A: No
Application cannulas	Yes	Duploject: Same Duo Set/Duo Set A: Same
Application catheter	No	Duploject: Same Duo Set/Duo Set A: Same
Technology Characteristics		
Syringe Type	Piston	Duploject: Same Duo Set/Duo Set A: N/A
Syringe Length	71-101 mm (Supplier: Codan)	Duploject: 72-85 mm (Supplier: B. Braun) for 2+4ml filling volume 73-87 mm (Supplier: B. Braun) for 10ml filling volume Duo Set/Duo Set A: N/A
Syringe Diameter	4-14 mm (Supplier: Codan)	Duploject: for 2+4ml filling volume: 11-14 mm (Supplier: B. Braun) for 10ml filling volume: 14-18 mm (Supplier: B. Braun) Duo Set/Duo Set A: N/A
Syringe Filling Volume[1]	0.5/1.0 mL, 2 mL, 5 mL	Duploject: 2 mL, 4 mL, 10 mL Duo Set/Duo Set A: N/A
Reconstitution Needle Gauge	21 G, 19 G	Duploject: 19 G, 18 G Duo Set/Duo Set A: N/A

[1] Previous nomenclature expressed volume per syringe. Now it is expressed as a total, based on the two syringes (e.g. 2 mL, 4 mL, 10 mL).

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Table 2. Device Comparison Table (Predicate vs. Proposed Devices)

Features	Duploject (Predicate) (K973510)	Proposed Devices
Reconstitution Needle Length	25 mm, 50 mm, 70 mm	Duploject: 50 mm, 70 mm Duo Set/Duo Set A: N/A
Needle Cover Color	Clear	Duploject: Same Duo Set/Duo Set A: N/A
Barrel Markings	Graduated	Duploject: Same Duo Set/Duo Set A: N/A
Barrel Transparency	Clear	Duploject: Same Duo Set/Duo Set A: N/A
Lubricant	Dow Corning 360 Medical Fluid	Duploject: Same Duo Set/Duo Set A: N/A
Principle of Operation	A joining piece, with a common plunger, connects two disposable syringes, and the contents are mixed in a common tip prior to dispensing.	Duploject: Same Duo Set/Duo Set A: Same
Biocompatibility	Cytotoxicity and leachable substances testing were conducted in accordance with ISO 10993-1. No evidence that any effects hazardous to the patient will arise by leachable ingredients and/or residues of the device components.	Duploject: Same Duo Set/Duo Set A: Same
Performance Characteristics		
Delivery Accuracy	1:1 delivery of fluids	Duploject: Same Duo Set/Duo Set A: Same
Conformance to release specifications	Functionality and packaging conform to external standards and Baxter specifications.	Duploject: Same Duo Set/Duo Set A: Same

*Note: Duplocath devices are accessories to the Duploject and Duo Set/Duo Set A systems and are not considered standalone devices

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DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet their acceptance criteria and support that the proposed devices are appropriately designed for their intended use.

Performance Data:

The performance of the devices has not changed since the original 510(k). The modifications do not impact the intended use or the fundamental scientific technology of the devices. The following bench tests were conducted to evaluate the effect of the modifications on the functional performance. All tests met the acceptance criteria. Performance data summaries are seen in Section 18.

Table 3. Performance Testing Summary

Test	Acceptance Criteria
Duploject	
Compatibility with Baxter's Two-Component Fibrin Sealant	Per Baxter test method
Functionality testing of all application systems which can be attached to the Duploject double syringe clip	Per Baxter test method
Functionality testing of y-piece with all applicable syringe types	Per Baxter test method
Determination of the loosening/unscrewing torque for the Luer lock of Duploject System	Per Baxter test method
Duo Set/Duo Set A	
Compatibility with Baxter's Two-Component Fibrin Sealant	Per Baxter test method
Functionality testing of y-piece with all applicable syringe types	Per Baxter test method
Determination of the loosening/unscrewing torque for the Luer lock of Duploject System	Per Baxter test method
Determination of the push-in and pull-out forces of the Duo Set plunger	Per Baxter test method
Determination of the compressive strength of the Duo Set plunger	Per Baxter test method
Duplocath	
Compatibility with Baxter's Two-Component Fibrin	Per Baxter test method

Table 3. Performance Testing Summary

Test	Acceptance Criteria
Sealant	
Cone Dimensions Verification according to ISO 594-1	Per Baxter test method
Functional Testing	Per Baxter test method
Dead Volume Comparison	Per Baxter test method
Tensile Bond Strength	Per Baxter test method
Packaging Seal Strength	Per Baxter test method
Packaging Peel Ability	Per Baxter test method
Packaging Dimensions Verification	Per Baxter test method

Biocompatibility:

Biocompatibility testing was conducted on fluid-path components representative of the final configuration and patient presentation. Testing was conducted in accordance with the FDA Regulations for Good Laboratory Practice (GLP), 21 CFR Part 58 to support the ISO 10993-1 qualification for external communicating devices with tissue/bone/dentin contact for a limited duration. The battery of testing included the following tests:

- Cytotoxicity (per ISO 10993-5)
- Sensitization (per ISO 10993-10)
- Irritation/Intracutaneous Reactivity (per ISO 10993-10)
- Acute Systemic Toxicity (per ISO 10993-11)
- Hemocompatibility (in Vitro Hemolysis) (per ISO 10993-4)
- Pyrogenicity (per ISO 10993-11)

Although not required for tissue/bone/dentin contact devices, an acute systemic toxicity test and a hemocompatibility test were performed as these devices may be considered as having indirect blood path contact. The non-fluid path devices (i.e.: Duploject syringe holder and Duo Set Syringe plungers) were tested separately from the fluid path devices, and not categorized according to ISO 10993-1. The non-fluid path devices were tested for Cytotoxicity (per ISO 10993-5). Testing was conducted in accordance with the FDA Regulations for Good Laboratory Practice (GLP), 21 CFR Part 58 ISO 10993-5 guidelines and USP <87>.

The overall results of these evaluations demonstrated that the devices are biocompatible for their intended use.

Sterility:

Duploject: The Duploject System devices are sterilized using ethylene oxide. The sterilization validation was performed according to the standard EN ISO 11135, "Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices" to provide a 10^{-6} Sterility Assurance Level (SAL).

Duo Set/Duo Set A: The Duo Set/Duo Set A devices are sterilized using gamma radiation. The sterilization validation was performed according to the standard EN ISO 11137, "Sterilization of Health Care Products- Requirements for Validation and Routine Control – Radiation Sterilization" to provide a 10^{-6} Sterility Assurance Level (SAL). The continued validity of the minimum sterilizing dose (MSD) is confirmed by periodic dose audit studies. In addition, routine bioburden testing prior to sterilization and bacterial endotoxins test is performed on this product.

Duplocath: The sterile packaging for the Duplocath devices is changing from single to double sterile packaging. The pack factor is also changing from 1 Duplocath product application tip per product carton to 3. Duplocath application devices are sterilized using gamma radiation. The sterilization validation was performed according to the standard EN ISO 11137, "Sterilization of Health Care Products- Requirements for Validation and Routine Control – Radiation Sterilization"to provide a 10^{-6} Sterility Assurance Level (SAL). The continued validity of the minimum sterilizing dose (MSD) is confirmed by periodic dose audit studies. In addition, routine bioburden testing prior to sterilization and bacterial endotoxins test is performed on this product.

Shelf-Life:

The Duploject, Duo Set/Duo Set A, and Duplocath devices have a 5 year shelf-life. Baxter has conducted aging studies to assess the proposed devices meet their intended shelf-life claim (5 years). Baxter has assessed that the devices packaging will maintain a sterile barrier and the devices' performance is maintained for the entirety of its intended shelf life claim.

CONCLUSION:

The non-clinical data demonstrate that the subject devices are substantially equivalent to the predicate devices.