K960047

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510(k) SUMMARY
AMENDED
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Name of Device: Piston Syringe 80 FMF
Common/Usual Name: Syringe
Trade/Proprietary Name: Brannon Pedi PortSyringe

The piston syringe, made available in a 3cc size, of this 510(k) notification, known as the Brannon Pedi PortSyringe (BPPS), is a combination of two legally marketed devices; (1) a piston syringe and (2) a blood specimen collection device (BSCD). The BSCD is integral with the plunger unit of the piston syringe with the BSCD communicating with the fluid chamber of the piston syringe via a centrally disposed and substantially narrow conduit. The fluid collection needle is sealed by a rubber sleeve. Appreciate that the needle is not manufactured by the applicant nor a manufacturing firm identified by the Applicant, but rather purchased from an FDA recognized manufacturer/distributor. Further appreciate that the BPPS is manufactured with identical material as the predicate piston syringe.

Sealing of the conduit with the fluid collection needle allows the piston-plunger unit and the barrel to function as a conventional syringe. Functional operation simply requires that one compression fits a hypodermic needle of any gauge to the distal nozzle tip of the barrel. One is then able to aspirate body fluids as the predicate piston syringe. After a given amount of fluid is aspirated into the barrel of the syringe, a minimal amount will suffice, a plurality of vacuum specimen tubes can be inserted into the tube-holder. The vacuum specimen tubes are advanced over the sleeved needle while stabilizing the tube-holder. In so doing, the vacuum within the specimen tube induces the piston-plunger unit to advance distally as the aspirated fluid is transferred to the vacuum specimen tube proximally.

If one desires blood for culturing, the blood aspirate is transferred to a vacuum blood culture bottle by inserting the hypodermic needle directly into the vacuum bottle as is done using a predicate piston syringe.

Regarding blood collection with simultaneous intravenous catheter insertion, the BPPS is securely fitted to the female hub of a percutaneously inserted intravenous catheter. One should briefly aspirate to assure vein patency. A plurality of vacuum specimen tubes are then inserted into the tube-holder as described in this summary.

The technological differences of the BPPS include fluid aspiration through the distal nozzle tip of the syringe barrel and subsequent transfer of the fluid aspirate through the piston-plunger unit and into a plurality of vacuum specimen tubes. The predicate piston syringe only allows influx and efflux of a fluid through the distal nozzle tip of its syringe barrel.

Regarding safety and effectiveness, a clinical trial was conducted at the University of Iowa Hospitals and Clinics (UIHC) in January of 1989. The title of the investigation was *"Safe, Simple & Efficient Fluid Extraction"*, with a report made in the UIHC publication Pacemaker, October 1989. The patient population included intensive care patients requiring multiple blood samples for vacuum specimen tubes and vacuum blood culture bottles. Use of the investigational device, which required some assembly, was as outlined in this summary. Appreciate that the new device of this summary does not require any assembly other than the attachment of a hypodermic needle. It was shown in this investigation that traditionally cumbersome phlebotomy procedures were made safer with improved efficiency, proficiency, and patient comfort.

Further appreciate that the Brannon Pedi PortSyringe meets all of the biocompatibility and performance standards (efficacy) of the predicate piston syringe and predicate BSCD, both devices are legally marketed and manufactured by Becton-Dickinson. The Brannon Pedi PortSyringe is manufactured with identical material as the predicate piston syringe and there is no deviation from this standard.

In conclusion, the above summary elucidates the physical characteristics which constitute the Brannon Pedi PortSyringe. The summary further shows by comparison that the intended use, fluid aspiration and transfer of the fluid aspirate to vacuum specimen tubes and bottles, is identical to the predicate piston syringe and the predicate BSCD. The clinical trial conducted at the UIHC demonstrates that the Brannon Pedi PortSyringe can be used safely and effectively in a manner identical to the predicate piston syringe and BSCD. Therefore, the Brannon Pedi PortSyringe of this 510(k) summary is claimed to be subtantially equivalent to a predicate piston syringe.