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510(k) SUMMARY

Name of Device: Piston Syringe 80 FMF
Common/Usual Name: Syringe
Trade/Proprietary Name: Brannon Arterio-Venous PortSyringe

The piston syringe, made available in a 6cc size, of this 510(k) notification, known as the Brannon Arterio-Venous PortSyringe, A-VPS, is a combination of two legally marketed devices; (1) a piston syringe, and (2) a blood specimen collection device, BSCD. Additionally, the A-VPS is identical to the Brannon PortSyringe K960049, except the A-VPS includes a centrally disposed inner cannula within its barrel. The BSCD is integral with the plunger unit, with the BSCD communicating with the inner lumen of an attached indwelling catheter via the centrally disposed narrow conduit of the plunger and the centrally disposed inner-cannula within the barrel of the syringe. 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 distributor. Further, appreciate that the A-VPS is manufactured with identical material as the Becton-Dickinson 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. The inner-cannula allows one to aspirate the sodium-heparin solution into the barrel of the syringe and around the outer surface of the inner-cannula. The amount of sodium-heparin aspirated into the lumen of the inner cannula is significantly small and does not adversely affect the laboratory results of the blood specimens, as evidence by the bench studies of this premarket notification. The fluid seal at the inner-cannula piston interface ensures that the sodium-heparin fluid aspirated into the barrel of the syringe remains separate from the lumen of the plunger-conduit. Given that the distal end of the A-VPS has a restricted opening, fluid within the barrel of the syringe will not flow out of the syringe barrel when a vacuum tube is inserted into the tube-holder portion of the A-VPS. Passive distal advancement of the piston-plunger unit, when a vacuum tube is inserted into the tube holder would require a significant amount of energy. This energy is not available through the vacuum tube, but rather, only manual manipulation of the A-VPS plunger. Functional operation simply requires that one locks the

female hub of an indwelling catheter to the distal luer-lock nozzle tip of the A-VPS syringe barrel. One is then able to aspirate the sodium-heparin solution into the barrel of the syringe, as with the predicate piston syringes. The small volume of sodium-heparin aspirated into the lumen of the inner-cannula, with the initial aspiration, is insignificant, as the total amount of sodium is 0.004mEq. This mEq amount is derived from a standard sodium-heparin solution with 154 mEq/L of NaCl, with a volume of the inner-cannula of ~0.031cc. Further, the user may discard the first draw of blood prior to obtaining any samples for laboratory testing. After a given amount of fluid is aspirated into the barrel of the syringe, and one observes whole blood in the distal portion of the syringe, 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 whole blood to flow from the inner lumen of the indwelling catheter, through the inner-cannula, through the plunger-conduit, and into the vacuum specimen tube, while the plunger remains in its most proximal position. The piston-plunger unit can then be slowly advanced distally to return the sodium-heparin solution to the catheter, or the syringe can be discarded without returning the sodium-heparin solution to the patient. One should aspirate only once with the A-VPS. Please review Figures 1-4.

The technological differences of the A-VPS include fluid aspiration through the distal nozzle tip of the syringe and into the syringe barrel. This fluid remains separate from whole blood induced to flow through the lumen of the inner cannula when a vacuum specimen tube is inserted into the tube-holder. This process of collecting blood differs from syringe K960049 in that with the A-VPS, a volume of fluid remains in the barrel of the syringe while blood is being transferred to a plurality of vacuum glass tubes. The predicate Becton-Dickinson 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 unit patients requiring multiple blood samples for vacuum specimen tubes and bottles. Use of the investigational device, now syringe K960049, which required some assembly, required the use of a hypodermic needle for percutaneous blood collection. Appreciate that the new device of this summary, the Brannon Arterio-Venous PortSyringe, does not require any assembly, other than attachment to an indwelling catheter, i.e., a central line or an arterial line. Attachment to a peripheral intravenous catheter is not an intended use. It was shown in the UIHC investigation that cumbersome phlebotomy procedures were made safer with improved efficiency and proficiency. Use of the A-VPS is substantially identical to syringe K960049. Syringe K960049 requires use of a hypodermic needle, while the syringe of

this notification requires the use of an indwelling catheter. Both syringes, K960049 and A-VPS, are identical in design construct and biocompatible. The effectiveness of the A-VPS is demonstrated in the bench investigation of the A-VPS' ability to separate fluid within the barrel of the syringe from a fluid within its plunger-conduit. During the bench investigation, the A-VPS was used in consecutive aspirations and there were no failures. The A-VPS differs from syringe K960049 only by the addition of the inner-cannula. Specifically, the inner-cannula is manufactured with identical material as the BSCD needle.

The bench investigation shows that a heparin fluid aspirated into the barrel of the syringe will remain separate from a fluid within the plunger-conduit. The ability of the rubber piston to maintain a hermetic seal at the level of the piston inner-cannula interface was demonstrated to be effective, as evidenced by the absence of detectable mixing of the two fluids in separate fluid chambers, chamber one (1) being the syringe barrel, and chamber two (2) being the plunger-conduit. The functional mechanism of this hermetic seal, at the level of the piston inner-cannula interface, is identical to the hermetic seal at the level of the piston-barrel interface, both are slidable fluid seals. Further, after fluid has been aspirated into the barrel of the A-VPS, an absolute requisite to retrieving this aspirated fluid is distal advancement of the plunger. The A-VPS is designed such that the piston will not advance distally when a vacuum tube is inserted into its tube holder. The blood that fills the vacuum specimen tube will come from the path of least resistance, i.e., the open lumen of the indwelling catheter. In this regard, the previously aspirated sodium-heparin solution will remain in the barrel of the syringe as whole blood for laboratory testing travels from the lumen of the indwelling catheter, through the inner-cannula, through the plunger-conduit, and into the vacuum specimen tube. The minute amount of sodium heparin aspirated into the inner-cannula with the initial aspiration is insignificant, as demonstrated with our bench testing. Thereafter the initial blood draw, the inner-cannula would be filled with whole blood. Subsequent blood draws can proceed as outlined in this premarket notification.

In conclusion, the above summary elucidates the physical characteristics that constitute the Brannon Arterio-Venous PortSyringe. The summary further shows by comparison that the intended use, fluid aspiration and subsequent transfer of whole blood to vacuum specimen tubes, is identical to the predicate B-D piston syringe, predicate syringe K960049, and the predicate BSCD. The clinical trial conducted at the UIHC demonstrates that the Brannon Arterio-Venous PortSyringe can be used safely and effectively in a manner identical to the predicate devices of this notification. Therefore, the Brannon Arterio-Venous PortSyringe of this 510(k) summary is claimed to be subtantially equivalent to a predicate piston syringe.