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Pre-Market Notification: STP™ System - PVA with Zinc

16 510(k) Summary

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Date of Summary Preparation	September 30, 1996
Device Name	
Trade or Proprietary Name	STP™ System- PVA with Zinc
Common Name	Fixative-preservative for intestinal parasite examination
Classification Name	Microbiological specimen collection and transport device (866.2900)
Intended Use	Collection, transport, preservation and preparation of stool specimens containing intestinal parasites for microscopic examination

16 510(k) Summary (Continued)

Description

The product contains two conical shaped centrifuge tubes. One tube contains Polyvinyl Alcohol with Zinc and the other 10% Buffered Formalin. A stand is provided to keep the tubes in the upright position.

Both tubes have a spoon contained within the tube which is attached to the cap. The cap/spoon is removed and used to obtain a sample of the stool specimen. The sample is placed into the centrifuge tubes and the cap/spoon assembly is securely closed. The collection tubes are shaken causing the mixing balls to disrupt the specimen allowing complete coverage of the specimen with the fixative.

The sample in PVA can be used for permanent staining techniques. The tube with the 10% Buffered Formalin also contains an integral filter which separates large debris from the specimen facilitating concentration of the specimen for wet mount examination.

The product is contained in a bag labeled with the biohazard symbol which can be used for transport of the tubes containing samples.

Substantial Equivalence Comparison

The Sage STP™ System-PVA with Zinc is substantially equivalent in principle and clinical performance to Meridian's Para-Pak® ZN-PVA/Formalin Kit for the routine collection, transport, preservation and preparation of stool specimens for identification of intestinal parasites by microscopic examination.

Similarities between the Sage and Meridian Products are listed below:

1. Both products have two tubes designed for the safe and convenient collection of a standardized quantity of stool specimen. They both have a spoon-in-cap design.
2. The tubes in both products contain general laboratory fixative solutions: One tube contains a Polyvinyl Alcohol with Zinc solution and the other tube contains 10% buffered Formalin.
3. The solutions have widespread use and acceptance for the purpose of fixing and preserving stool specimens. PVA allows permanent stain slides to be prepared from the specimen. Formalin is a fixative that is used primarily for preserving a specimen which will be concentrated and wet mounted on a slide.[1]

16 510(k) Summary (Continued)

Performance Test Summary

Test Name:	Performance Evaluation
Purpose:	To evaluate the functional performance of Sage's Stool Transport Processing System - Polyvinyl Alcohol with Zinc, using a standardized testing procedure.
Summary of Method:	Specimens were evaluated at independent clinical laboratories. The quality control test method described in the instruction sheet for the product was used for assessing functional performance. This method is based on the procedure reported by Garcia and Bruckner[1] where white blood cells are used in lieu of parasites. White blood cells (buffy coat from uncoagulated human blood with high WBC count) are added to product tubes containing human stool specimens. Written instructions were then followed for the preparation and microscopic evaluation of permanent slides and wet mounts. Product function was evaluated as either satisfactory or unsatisfactory. For a satisfactory functional evaluation the smear must adhere well to the glass slides after permanent staining to allow for a thorough microscopic examination, and the added cells from the human buffy coat must be well-fixed and display typical morphology and color when the permanent stains and wet mounts are examined under a microscope.
Conclusion:	The STP™ System - PVA with Zinc, when used according to current instructions, results in a successful microscopic examination of human stool specimens for parasites.

1 Garcia, L.S. and Bruckner, D.A., Diagnostic Medical Parasitology, 2nd Edition, Washington, D.C., American Society for Microbiology, 1993