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Pre-Market Notification: STP™ System - SAF

**16 510(k) Summary**

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**Date of Summary Preparation** September 30, 1996

**Device Name**

Trade or Proprietary Name STP™ System- SAF

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

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## 16 510(k) Summary (Continued)

### Description

The product is comprised of a conical shaped centrifuge tube containing Sodium Acetate-Acetic Acid-Formalin (SAF) solution. A stand is provided to keep the tube in the upright position.

A spoon is attached to the cap and contained within the tube. The cap/spoon is removed and used to obtain a sample of the stool specimen. The sample is placed into the centrifuge tube and the cap/spoon assembly is securely closed. The collection tube is shaken causing the mixing balls to disrupt the specimen allowing complete coverage of the specimen with the fixative. The tube also contains an integral filter which separates large debris from the specimen and facilitates concentration of the specimen. The sample can be used for permanent staining, concentration, and/or wet mount procedures.

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

### Substantial Equivalence Comparison

The Sage STP™ System - SAF is substantially equivalent in principle and clinical performance to Meridian's Para-Pak® SAF Fixative 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 one tube 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 a Sodium Acetate-Acetic Acid -Formalin solution.
3. The solutions have widespread use and acceptance for the purpose of fixing and preserving stool specimens. Both products allow for the standard methods of sample preparation for microscopic examination of stool specimens for parasites by permanent staining and/or concentration and wet mount.<sup>1</sup>

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## 16 510(k) Summary (Continued)

### Performance Test Summary

<b>Test Name:</b>	Performance Evaluation
<b>Purpose:</b>	To evaluate the functional performance of Sage's Stool Transport Processing System - Sodium Acetate-Acetic Acid-Formalin, using a standardized testing procedure.
<b>Summary of Method:</b>	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 <sup>1</sup> 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.
<b>Conclusion:</b>	The STP™ System - SAF, when used according to current instructions, results in a successful microscopic examination of human stool specimens for parasites.

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

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