

K960997

SUMMARY OF SAFETY AND EFFECTIVENESS

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1. CONTACT NAME AND ADDRESS

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2. DEVICE NAME

Classification Name: Transport System, Aerobic/Anaerobic
Common Name: Sterile Microbiological Specimen
Collection and Transport System
Proprietary Name: Starswab Culture Collection and
Transport System

3. PREDICATE DEVICE

Amies CultureSwab™ Transport Systems with and without charcoal are marketed by Difco Laboratories, P.O. Box 331058, Detroit MI, 48232-7058, U.S.A.

4. DEVICE DESCRIPTION

The Starswab Culture Collection and Transport System is self-contained, sterile and intended for maintaining the viability of clinical specimens during transportation to the laboratory. The medium contains sodium thioglycollate as a reducing agent and the moisture and media depth provide an ideal environment for the survival of both aerobic and anaerobic microorganisms.

5. SUBSTANTIAL EQUIVALENCE DETERMINATION

The Starswab Culture Collection and Transport System is similar in design, manufacturing and intended usage to Amies Medium and Amies Medium without charcoal currently manufactured and marketed by Difco Laboratories. This substantial equivalence claim is supported by manufacturing, medium formulation, packaging and clinical evaluations. Known inocula of ATCC type cultures and clinically significant microorganisms were inoculated in the Starswab and Difco transport media and stored at room temperature for 24 and 48 hours prior to subculturing onto an appropriate culture media then checked for growth characteristics. No significant differences in recovery were detected between samples obtained from Starswab vs. Difco transport medium and the results were judged to be equivalent.