

DEC 24 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

DATE OF SUMMARY PREPARATION: 17 November, 1996

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DEVICE NAME: CULTURE-PAK™
Collection and Transport System,
Modified Amies Transport Media

DEVICE CLASSIFICATION: Class I, General Controls

COMMON NAME: Microbiological specimen collection and
transport device

PREDICATE DEVICE(S): Culture Collection and Transport
Device (K881105), CULTURE-PAK™
Collection and Transport System, Modified
Stuart's Media (K932337/S1 and K936078)
Medical Packaging Corporation
Camarillo, CA

Intended Use

Medical Packaging Corporation's CULTURE-PAK™ Collection and Transport System, with Modified Amies Transport Media, is intended for use as a disposable, sterile culture collection device for use in the collection, preservation, and transportation of microbiological specimens.

Substantial Equivalence

Medical Packaging Corporation's CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media, is substantially equivalent to Medical Packaging Corporation's Culture Collection and Transport Device (K881105), and CULTURE-PAK™ Collection and Transport System, Modified Stuart's Media (K936078) and (K932337/S1). Listed devices are intended to collect, preserve, and transport clinical specimens to the laboratory for microbiological analysis. Devices are composed of two plastic parts:

- The top plastic part holds 0.4 mL of clinical transport media and a plastic shaft, Rayon® tipped swab. Configuration of the CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media, will also provide two plastic shaft, Rayon® tipped swabs; an aluminum shaft, Rayon® Mini-Tip swab for collection of either male urethral or nasopharyngeal specimens; or a CytoSoft™ cytology brush.
- The bottom plastic part protects the swab(s) or brush (*hereafter referred to as: collection device*) and fits tightly into the top plastic part. The CULTURE-PAK™ and the Culture Collection and Transport Device are packaged sterile. Sterilization is conducted at SteriGenics, International, Inc., and validated by North American Science Associates, Inc. for both devices.

The methods for use are similar for the CULTURE-PAK™ and the Culture Collection and Transport Device. The two plastic parts are pulled apart, exposing the swab(s) or brush. After the culture is collected, the bottom is refitted into the top. The media seal is broken and the fluid is forced into the bottom extrusion to keep the *collection device* moist for up to 48 hours at room temperature.

The primary differences between Medical Packaging Corporation's CULTURE-PAK™ Collection and Transport System and the Culture Collection and Transport Device are how the media is contained, how to free the media so it will flow down into the bottom plastic part, and the provision of additional specimen collection devices as configured. The CULTURE-PAK™ has a plastic plug that holds the media in the top part. The top is bent 45 ° to break the plug allowing the media to flow into the bottom. The Culture Collection and Transport Device has a glass ampule that holds the media in the top plastic part. The top is squeezed to crush the ampule allowing the media to flow into the bottom. The CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media will also be available with an aluminum shaft Rayon® Mini-Tip rayon swab and a CytoSoft™ cytology brush.

510(k) Notification • 17 November, 1996
Medical Packaging Corporation
CULTURE-PAK™ Collection and Transport System
with Modified Amies Media

All used materials should be treated as potentially infectious and biohazardous. Proper handling and disposal methods should be employed.

Patricia V. Willis Date: 11-18-96
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