

K970597

510(k) Notification • 12 February, 1997  
Medical Packaging Corporation  
CULTURE-PAK™ Collection and Transport System  
with Clinical Transport Media  
(Cary-Blair Transport Media Option)

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**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:** 12 February, 1997

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**DEVICE NAME:** CULTURE-PAK™  
Collection and Transport System,  
Clinical Transport Media  
(Cary-Blair Transport Media Option)

**DEVICE CLASSIFICATION:** Class I, General Controls

**COMMON NAME:** Microbiological specimen collection and transport device

**PREDICATE DEVICE(S):** Modified Stuart's Media (K932337/S1 and K936078 ), and CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media, K964637.  
Medical Packaging Corporation  
Camarillo, CA

**Intended Use**

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

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### Substantial Equivalence

Medical Packaging Corporation's CULTURE-PAK™ Collection and Transport System, Clinical Transport Media, Cary-Blair Transport Media option, is substantially equivalent to Medical Packaging Corporation's CULTURE-PAK™ Collection and Transport System, Modified Stuart's Media (K936078) and ( K932337/S1), and CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media, K964637. 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, Clinical 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.
- 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™ Collection and Transport System is 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 the same for the CULTURE-PAK™ Collection and Transport System, Modified Stuart's Media (K936078) and ( K932337/S1), CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media, K964637, and CULTURE-PAK™ Collection and Transport System, Clinical Transport Media, Cary-Blair Transport Media option. The two plastic parts are pulled apart, exposing the swab(s). 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 72 hours at room temperature.

The primary differences between Medical Packaging Corporation's CULTURE-PAK™ Collection and Transport System with Modified Stuart's Transport Media, Modified Amies Media and the CULTURE-PAK™ Collection and Transport System, Clinical Transport Media, Cary-Blair Transport Media, are (1) the media options available, and (2) the addition of a dropper tip configuration. The CULTURE-PAK™ has a plastic plug that holds the media in the top part of the device. The top is bent 45 ° to break the plug allowing the media to flow into the bottom. The CULTURE-PAK™ Collection and Transport System, Clinical Transport Media will also be available with an aluminum shaft Rayon® Mini-Tip rayon swab.

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

Patricia V. Willis Date: 12 FEBRUARY 1997  
Patricia V. Willis  
Director, Customer Service and Regulatory Affairs