K993161

NOV - 9 1999

510(k) SUMMARY
FOR
COPAN EASY-SWAB
COLLECTION AND TRANSPORT SYSTEM

1. SPONSOR

Copan Diagnostics Inc.
2175 Sampson Avenue, Unit 124
Corona, CA 91719

Contact Person: Norman Sharples
Telephone: 1-800-216-4016

Date Prepared: September 21, 1999

2. DEVICE NAME

Proprietary Name:	Copan Easy-Swab Collection and Transport System
Common/Usual Name:	Specimen Collection and Transport System
Classification Name:	Microbiological Specimen Collection and Transport Device

3. PREDICATE DEVICES

Becton Dickinson Culturette EZ and Culturette EZ II Transport Products subject of K913789.

4. DEVICE DESCRIPTION

The Copan Easy-Swab is offered in two configurations. The Copan Easy-Swab I is offered with a single swab applicator and the Copan Easy-Swab II is offered with two swab applicators. The Copan Easy-Swab is composed of a sterile peel pouch containing one or two swab applicators inside the transport tube. The swab applicator incorporates a polyurethane foam tip on a plastic shaft secured to a cap. The tube is manufactured from polypropylene.

To use the Copan Easy-Swab Collection and Transport System, the sterile peel pouch is opened and discarded. The applicator swab is removed from the tube

and used to collect the clinical specimen. During specimen collection, the applicator tip should only touch the area where the infection is suspected. The applicator swab is returned to the transport tube, the cap firmly closed, and the specimen sent to the laboratory for analysis. After use, the tubes and swabs must be disposed of according to hospital or laboratory procedures for infectious waste.

5. INTENDED USE

The Easy-Swab is a sterile, single-use specimen collection chamber intended to preserve the viability of aerobic microorganisms after their collection and during their transport from the collecting area to the laboratory. These devices are intended for the collection, transport, and preservation of aerobic clinical specimens for bacteriological examination. The Copan Easy-Swab Collection and Transport System products are designed to support the viability of a wide variety of clinically important aerobic bacteria.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Copan Easy-Swab products are substantially equivalent in design, intended use, and overall function to other commercially distributed products used for the collection and transport of aerobic bacteria. Specifically, the Copan Easy-Swab products are substantially equivalent to the Becton Dickinson Culturette EZ and Culturette EZ II Collection and Transport System products subject of K913789.

The Copan Easy-Swab Collection and Transport System products and the substantially equivalent products are all sterile, single-use devices intended for use in the collection, transport and preservation of aerobic specimens for bacteriological examination. The Copan Easy-Swab Collection and Transport System products and the predicate devices are equivalent in design and function in that single or double swab applicators are used for collection of the specimen and the swab applicator(s) then inserted into an empty tube for transport and preservation.

Both the Copan Easy-Swab applicators and the Becton-Dickinson Culturette EZ applicators use polyurethane as the tip material. All of the products use color-coded caps for ease in product recognition.

7. PERFORMANCE TESTING

Studies were conducted to evaluate the performance characteristics of the Copan Easy-Swab. Recovery studies were performed using Copan and comparative products to determine the ability of the products to maintain viability of aerobic bacteria during storage and use. Recovery studies were performed using a variety of aerobic organisms. Swabs were dosed with inoculum and inserted into the transport tube. The tubes were stored at room temperature prior to sub-culturing onto appropriate media. All organisms tested remained viable for at least 24 hours when maintained at room temperature.

Stability studies were performed on the Copan Easy-Swab products to support performance for a 24-month expiration-dating period. All testing was performed at least 24 months after manufacture and gamma radiation sterilization of the finished product The test results demonstrate the stability of the Easy-Swab device over its 24-month expiration-dating period.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 9 1999

Copan Diagnostics, Inc.
c/o Ms. Maryl McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K993161
Trade Name: Copan Easy-Swab Collection and Transport System
Regulatory Class: I
Product Code: JTY
Dated: September 21, 1999
Received: September 22, 1999

Dear Ms. Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K993161

Device Name: Copan Easy-Swab Collection and Transport System

Indications for Use:

The Copan Easy-Swab Collection and Transport System products are sterile, single-use specimen collection chambers intended to preserve the viability of aerobic microorganisms after their collection and during their transport from the collecting area to the laboratory. These devices are intended for the collection, transport, and preservation of aerobic clinical specimens for bacteriological examination. The Copan Easy-Swab Collection and Transport System products are designed to support the viability of a wide variety of clinically important aerobic bacteria.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993161

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109) Optional Format 1-2-96