K972448

510(k) Summary
for
Copan Venturi Transystem Amies Medium Without Charcoal

1. Applicant

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

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

Date Prepared: June 27, 1997

2. Device Name

Proprietary Name: Copan Venturi Transystem Amies Medium Without Charcoal

Common/Usual Name: Specimen Collection and Transport System

Classification Name: Microbiological Specimen Collection and Transport Device

Classification Status: Class I

3. Predicate Devices

- Starswab Culture Collection and Transport System
  Starplex Scientific
  K960997

- Port-A-Cul Specimen Collection and Transport Products
  Becton Dickinson
  K854986

4. Device Description

The Copan Venturi Transystem Amies Medium Without Charcoal products are comprised of a sterile peel pouch containing a swab applicator and a tube containing the Amies Transport Medium Without Charcoal and are offered in six models. The only difference in the six models is the type of applicator used for the collection of the bacteriological sample. The applicator shafts vary for facilitation of the collection of the specimen from various sites of the patient. The six types of Copan Venturi Transystem Amies Medium Without Charcoal products are:

- **Product Code 108C** with plastic applicator
- **Product Code 134C** with two plastic applicators
- **Product Code 110C** with regular aluminum applicator
- **Product Code 124C** with soft aluminum applicator
- **Product Code 128C** with slim paper applicator
- **Product Code 190C** with flexible twisted wire applicator

5. Intended Use

The Copan Venturi Transystem Amies Medium Without Charcoal products are sterile, single-use specimen collection chambers intended to preserve the viability of 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 clinical specimens for bacteriological examination. Copan Venturi Transystem Amies Medium Without Charcoal is designed to support the viability of a wide variety of clinically important aerobic and anaerobic bacteria.

6. Technological Characteristics

The Copan Venturi Transystem Amies Medium Without Charcoal Products are substantially equivalent in design, intended use, and overall function to the predicate devices identified above.

The Copan Venturi Transystem Amies Without Charcoal products and the substantially equivalent products are all sterile, single-use devices intended for use in collection, transport and preservation of clinical specimens for bacteriological examination. The proposed and predicate devices are equivalent in design and function in that single or double swab applicators are used for collection of the specimen, different types of applicator shafts are available, and color-coded caps are used for ease of product recognition. The Copan and Starplex devices are also similar in that they incorporate design features intended to enhance the viability of anaerobic bacteria.

7. Performance Testing

Studies were conducted to evaluate the performance characteristics of the Copan Venturi Transystem Amies Medium Without Charcoal products. Recovery studies were performed using Copan and comparative products to determine the ability of the products to maintain viability of anaerobic bacteria during storage and use. Additional studies were performed to determine the ability of the packaging to retard oxygen penetration over the shelf life of the Copan products. The results of this testing demonstrated acceptable performance of the proposed device under the intended conditions of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Copan Diagnostics, Inc.
c/o Medical Device Consultants, Inc.
Atten: Cynthia A. Sinclair, RAC
Senior Staff Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

AUG 20 1997

Re: K972448
Trade Name: Copan Venturi Transystem Amies Medium without Charcoal
Regulatory Class: I
Product Code: JSL
Dated: June 27, 1997
Received: June 30, 1997

Dear Ms. Sinclair:

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 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): _____

Device Name: Copan Venturi Transystem Amies Medium Without Charcoal

Indications For Use:

The Copan Venturi Transystem Amies Medium Without Charcoal products are sterile, single-use specimen collection chambers intended to preserve the viability of 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 clinical specimens for bacteriological examination. Copan Venturi Transystem Amies Medium Without Charcoal is designed to support the viability of a wide variety of clinically important aerobic and anaerobic bacteria.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972448

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)