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AUG 13 2003

510(k) SUMMARY

Sponsor: Starplex Scientific Inc.
50 Steinway Blvd.
Etobicoke, Ontario, Canada M9W 6Y3

Sponsor Contact: Mehdi Karamchi, Director, QA/Regulatory Affairs
Tel: 416-674-7474 ext. 3018
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Date Prepared: July 17, 2003

Device Classification Name

Transport System Aerobic

Common Name

Sterile swab culture collection and transport system for virus, chlamydia and mycoplasma.

Proprietory Name

Multitrans Culture Collection and Transport System

Legally marketed device. Multitrans (code S160) Docket # K962843

Device Description

Starswab Multitrans Collection and Transport System provides a safe and convenient way to collect and transport clinical specimens without leakage under optimum storage conditions. The osmotically balanced buffered medium will maintain the viability of viral, chlamydia and mycoplasma specimens during transportation to the laboratory. Antibiotics are incorporated into the medium to inhibit growth of competing bacteria and yeast. The addition of serum albumin provides a stabilizing effect. The high concentration of sucrose aids in the preservation of viruses and chlamydia if the specimens are frozen (-70°C) for prolonged storage.

Statement of Intended Use

Multitrans is intended for the collection and transportation of viruses, chlamydia and mycoplasmas obtained from clinical specimens.

Description of Change

The recommended storage condition prior to use has been changed from 2-8°C to 2-25°C.

Summary of Performance Data

Clinical evaluation has been carried out by the Ontario Provincial Public Health Laboratory to ensure performance characteristics of the product held under new storage conditions is not compromised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 13 2003

Mehdi Karamchi, B.Sc. RM (CCM)
Director, QA/Regulatory
Starplex Scientific Inc.
50 Steinway Boulevard, Etobicoke
Ontario, CANADA M9W 6Y3

Re: k032246
Trade/Device Name: Starswab Multitrans Collection and Transport System (Cat. No. S160)
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I
Product Code: JSM
Dated: July 17, 2003
Received: July 24, 2003

Dear Mr. Karamchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K032246

Device Name: Starswab Multitrans Collection and Transport System (Cat. No. S160)

Indications of Use:

The Starswab Multitrans Collection and Transport System (Cat. No. S160) is intended for the collection and transportation of Chlamydia, Mycoplasmas and viruses obtained from clinical specimens.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sally A. Hojvat 8/12/03 K032246

Division Sign-Off

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

Office of In Vitro Diagnostic Device Evaluation and Safety

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