DEC 3 0 2008

8.0 510(k) Summary for Medical Wire Virocult® Virus Collection and Transport System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K082472.

1. Submitter

Medical Wire & Equipment Company (Bath) Ltd.,

Leafield Industrial Estate,
Corsham,
Wiltshire,
SN13 9RT
United Kingdom

Contact person	David Ellis
Telephone	+441225810361
Date prepared	28 July 2008

2. Device Name

Proprietary Name	Medical Wire & Equipment Virocult®
Common / Usual Name	Virus Collection and Transport Device
Product Code	LIO
FDA Device Regulation Number and Classification Name	Sec. 866.2900 Microbiological Specimen collection and transport device

3. Predicate Devices

Becton Dickinson Viral Culturette™	(K800832)
Copan Viral Transystem ™	(K001780)

4. Device Description

Each Virocult® device comprises a sterile peel pouch containing a rayon- tipped swab used to collect the sample and a tube containing an open cell polyurethane pad soaked with Virocult® virus transport medium. After sampling, the swab applicator is placed inside the tube, where the bud is bathed with the liquid from the foam pad.

Virocult® medium consists of a phosphate-buffered balanced salt solution, glucose, lactalbumin hydrolysate to stabilise the virus particles, and antibiotics to inhibit the growth of other microorganisms that may be present in the clinical specimen.

The rayon- tipped swab will suit most general applications such as mouth, nose, throat and skin.

To use Virocult®, the sterile peel pouch is opened, and the cap removed from the transport tube. The applicator swab is removed from the pouch and used to collect the clinical specimen. During specimen collection, the applicator should only touch the area where the infection is suspected.

5. Intended Use

Medical Wire & Equipment Virocult® Virus Collection and Transport System is intended to preserve the viability and infectivity of viral specimens for viral culture after their collection and during transport from the collection site to the testing laboratory. Virocult specimens are processed using standard clinical laboratory operating procedures for viral and cell culture.

6. Technological characteristics and substantial equivalence

Medical Wire & Equipment's Virocult® products are substantially equivalent in design, intended use, and overall function to other FDA approved commercially distributed products used for the collection and transport of viruses. Specifically Virocult® products are equivalent to the Becton Dickinson Viral Culturette (K800832), and the the Copan Viral Transystem (K001780).

Medical Wire & Equipment's Virocult® device, and the substantially equivalent products are all sterile, single use devices intended for use in the collection, transport, and preservation of microbial specimens for culture. The candidate and predicate devices are equivalent in design and function in that single applicators are used for collection of the specimen and the swab applicator is then inserted into a tube containing medium for transport and preservation. Both Virocult®, and the predicate devices are offered in collection kit formats with specimen collection swabs.

7.0 Performance testing

Virocult® virus transport swabs have been tested in accordance with CLSI (NCCLS) 'Quality Control of Microbiological Transport Systems'; Approved Standard M40-A. Tests were done to simulate transport at $4^{O}C$ and at $23^{O}C$. The tests were performed both on swabs within date, and swabs which had gone 2 months beyond their expiry date.

Stability studies were performed on Medical Wire & Equipment's Virocult® products to support performance for a 12-month expiration date. Recovery testing, pH testing, toxicity testing and visual inspection were performed which demonstrated the stability of Medical Wire & Equipment's Virocult® over its 12 month shelf life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Douglas Shedden
Technical & Development Manager
Medical Wire & Equipment Company (Bath) Ltd.
Potley Lane,
Corsham Wiltshire, SN13 9RT
United Kingdom

DEC 30 2008

Re: K082472
Trade/Device Name: VIROCULT® *Viral Specimen Transport Device*
Regulation Number: 21 CFR 866.2900
Regulation Name: Microbiological specimen collection and transport device
Regulatory Class: Class I
Product Code: LIO
Dated: December 8, 2008
Received: December 10, 2008

Dear Mr. Shedden:

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082472

Device Name: Medical Wire & Equipment Virocult® Virus Collection and Transport System

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k082472