JAN - 6 2005

1.0 510(k) Summary

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: K042479

1.1 Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-3482
Fax: (585) 453-3368

Contact Person: Carey A. Mayo, M.S., RAC

1.2 Date of Preparation: September 9, 2004

1.3 Device Proprietary Name(s)

Trade Name(s):
VITROS Chemistry Products GENT Reagent
VITROS Chemistry Products Calibrator Kit 13
VITROS Chemistry Products TDM Performance Verifier I, II, and III

Common Name(s): Gentamicin assay and controls

1.4 Classification Name(s)

Gentamicin Test System: Class II (21 CFR 862.3450)
Calibrators: Class II (21 CFR 862.3200)
Assayed Controls: Class I (21 CFR 862. 3280)

1.5 Predicate device

The VITROS Chemistry Products GENT reagent and calibrators are substantially equivalent to the SYVA® Emit® 2000 Gentamicin Plus Assay and Gentamicin Plus Calibrators (Dade Behring, Inc.).

The VITROS Chemistry Products TDM Performance Verifiers are substantially equivalent to the VITROS Chemistry Products TDM Performance Verifiers currently in commercial distribution.

1.6 Device description

The VITROS Chemistry Products GENT Reagent, VITROS Chemistry Products Calibrator Kit 13, and the VITROS Chemistry Products TDM Performance Verifiers are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS GENT assay. VITROS Chemistry Products GENT Reagent is a dual chambered package containing ready-to-use liquid reagents that are used in a two-step reaction to quantitatively measure gentamicin.

VITROS Chemistry Products Calibrator Kit 13 and TDM Performance Verifiers are packaged and sold separately.

VITROS Chemistry Products Calibrator Kit 13 is a liquid ready to use calibrator set for gentamicin. Each kit contains one bottle each of six (6) levels. The level 1 bottle (zero level) contains 5 milliliters. The level 2 through 6 bottles each contain 2 milliliters.

VITROS Chemistry Products TDM Performance Verifier I, II and III are liquid ready to use controls with assayed values published for each lot. The controls are prepared from bovine serum with therapeutic drugs and preservatives added. The product is sold in separate kits of Level I, II and III. Each kit contains 6 vials (2 mL each).

1.7 Device intended use(s)

VITROS Chemistry Products GENT Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products GENT Reagent is used to quantitatively measure gentamicin (GENT) concentration in human serum and plasma. Serum or plasma gentamicin measurements are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.

VITROS Chemistry Products Calibrator Kit 13: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 13 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of gentamicin (GENT).

VITROS Chemistry Products TDM Performance Verifier I, II and III: For *in vitro* diagnostic use only. VITROS TDM Performance Verifier is an assayed control used to monitor performance of ACET, CRBM, DGXN, PHBR, PHYT and GENT on VITROS Chemistry Systems.

1.8 Comparison to predicate device: Reagent and Calibrators

The VITROS Chemistry Products GENT Reagent and VITROS Chemistry Products Calibrator Kit 13 and are substantially equivalent to the SYVA Emit 2000 Gentamicin Plus Assay and the SYVA Emit 2000 Gentamicin Plus Calibrators, which were cleared by FDA (K962519) for IVD use.

The relationship between the VITROS GENT assay and the predicate device, determined by least squares linear regression, is:

VITROS GENT assay = 1.00 X - 0.0138 μg/mL, with a correlation coefficient of 0.993, where X is the predicate device.

In addition to the correlation studies, studies were performed to determine the precision, expected values, linearity, and specificity of the VITROS GENT assay (refer to the VITROS Chemistry Products GENT Reagent Instructions for Use for summaries of the results of these studies).

The table below lists the characteristics of the VITROS Chemistry Products GENT assay and the predicate device.

Device Characteristic	VITROS GENT Assay (New device)	SYVA Emit 2000 Gentamicin Plus Assay (Predicate device)
Intended Use	Quantitative measurement of gentamicin	Quantitative measurement of gentamicin
Basic principle	Homogeneous enzyme immunoassay	Homogeneous enzyme immunoassay
Reportable Range	0.6 – 10 μg/mL	0.25 – 10 μg/mL
Reagents	Liquid ready to use	Liquid ready to use
Instrumentation	VITROS 5,1 FS Chemistry System	SYVA-30R Biochemical System
Sample type	Serum and plasma	Serum and plasma

1.9 Comparison to predicate device: Performance Verifiers

The VITROS Chemistry Products TDM Performance Verifiers are identical in intended use, base matrix, storage and handling and instructions for use as the previously cleared VITROS Chemistry Products TDM Performance Verifiers (K042476). The labeling will be updated to add assigned values for gentamicin so that the TDM Performance Verifiers may be used with the VITROS Chemistry Products GENT assay.

1.10 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products GENT reagent, VITROS Chemistry Products Calibrator Kits 13 and the VITROS Chemistry Products TDM Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 6 2005

Ms. Carey A. Mayo, M.S., RAC
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k042479
Trade/Device Name: VITROS Chemistry Products GENT Reagent
VITROS Chemistry Products Calibrator Kit 13
VITROS Chemistry Products TDM Performance
Verifiers I, II, and III
Regulation Number: 21 CFR 862.3450
Regulation Name: Gentamicin test system
Regulatory Class: Class II
Product Code: LCD, DLJ, DIF
Dated: December 7, 2004
Received: December 8, 2004

Dear Ms. Mayo:

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 (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use

510(k) Number (if known): K042479

Device Name:

1. VITROS Chemistry Products GENT Reagent
2. VITROS Chemistry Products Calibrator Kit 13
3. VITROS Chemistry Products TDM Performance Verifiers I, II, and III

Indications for Use:

1. For *in vitro* diagnostic use only. VITROS Chemistry Products GENT Reagent is used to quantitatively measure gentamicin (GENT) concentration in human serum and plasma. Serum or plasma gentamicin measurements are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.
2. For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 13 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of gentamicin (GENT).
3. For *in vitro* diagnostic use only. VITROS TDM Performance Verifier is an assayed control used to monitor performance of ACET, CRBM, DGXN, PHBR, PHYT and GENT on VITROS Chemistry Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042479