

APR 24 2006

5.0 510(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: K060940

5.1 Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Telephone: (585) 453-4041
Facsimile: (585) 453-3368
Contact Person: Marlene Hanna

5.2 Date of Preparation: April 5, 2006

5.3 Device Proprietary Names:

Trade Names: VITROS Chemistry Products Calibrator Kit 99
VITROS Chemistry Products AAT/HPT Performance Verifier I, II, and III
Common Name: Calibrators and controls

5.4 Classification Names

Classification Name: Calibrator (21 CFR 862.1150): Class II

Classification Name: Quality Control material (assayed and unassayed) (21 CFR 862.1660): Class I: Reserved

5.5 Predicate devices

The VITROS Chemistry Products Calibrator Kit 99 (new intended use), and VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, and III are substantially equivalent to the VITROS Chemistry Products Calibrator Kit 99 (current product), and VITROS Chemistry Products AAT Performance Verifiers I, II, and III respectively. The predicate devices were both previously cleared by the FDA (K052819) for IVD use.

5.6 Device description

VITROS Chemistry Products Calibrator Kit 99

VITROS Chemistry Products Calibrator Kit 99 is a five level set of fluids used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of α 1-antitrypsin (AAT), and haptoglobin (HPT) using VITROS Chemistry Products AAT and HPT Reagents. VITROS Chemistry Products Calibrator Kit 99 is prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added.

VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, and III

VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, and III is a three level set of assayed liquid controls used to monitor the performance of α 1-antitrypsin (AAT), and haptoglobin (HPT) measurements, using VITROS Chemistry Products AAT and HPT Reagents, respectively, with the VITROS 5,1 FS Chemistry Systems. The VITROS AAT/HPT Performance Verifiers are prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added.

5.7 Device intended use

VITROS Chemistry Products Calibrator Kit 99

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of proteins in body fluids.

VITROS Chemistry Products AAT/HPT Performance Verifier I, II, and III

For *in vitro* diagnostic use only. VITROS Chemistry Products AAT/HPT Performance Verifiers are assayed controls used to monitor the performance of protein measurements in body fluids on VITROS 5,1 FS Chemistry Systems.

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5.8 Comparison to predicate device

The VITROS Chemistry Products Calibrator Kit 99 (new intended use), and VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, and III are substantially equivalent to the VITROS Chemistry Products Calibrator Kit 99 (current product), and VITROS Chemistry Products AAT Performance Verifiers I, II and III, respectively. The predicate devices were both previously cleared by the FDA (K052819) for IVD use.

Tables 1 and 2 provide similarities and differences between the new devices and predicate devices.

Table 1 lists the similarities and differences of the device characteristics between new device VITROS Chemistry Products Calibrator Kit 99 (new intended use) and predicate device, VITROS Chemistry Products Calibrator Kit 99 (current Product).

TABLE 1

Device Characteristic	VITROS Calibrator Kit 99 (New intended use) New Device#1	VITROS Calibrator Kit 99 (Current Product) Predicate Device#1
Intended Use Statement	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of proteins in body fluids.	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of α_1 -antitrypsin (AAT).
Analytes	α_1 -Antitrypsin(AAT), Haptoglobin (HPT)	α_1 -Antitrypsin (AAT)
Traceability	BAM-IRMM-LGC (Bundesanstalt für Materialforschung und -prüfung / Institute for Reference Methods and Materials / Laboratory of the Government Chemist) ERM- DA470 Reference Material ¹	BAM-IRMM-LGC (Bundesanstalt für Materialforschung und -prüfung / Institute for Reference Methods and Materials / Laboratory of the Government Chemist) ERM- DA470 Reference Material ¹
Number of levels	Five	Five
Format	Liquid ready to use	Liquid ready to use
Fluid Matrix	Processed human serum	Processed human serum

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Table 2 lists the similarities and differences of the device characteristics between new device VITROS AAT/HPT Performance Verifiers and predicate device, VITROS AAT Performance Verifiers.

TABLE 2

Device Characteristic	VITROS AAT/HPT Performance Verifiers I, II and III New device #2	VITROS AAT Performance Verifiers I, II, and III Predicate device #2
Intended Use Statement	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products AAT/HPT Performance Verifiers are assayed controls used to monitor performance of protein measurements in body fluids with VITROS 5,1 FS Chemistry Systems.	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products AAT Performance Verifiers are assayed controls used to monitor performance of VITROS AAT Reagents on VITROS 5,1 FS Chemistry Systems.
Analytes	α_1 -Antitrypsin(AAT), Haptoglobin (HPT)	α_1 -Antitrypsin (AAT)
Number of levels	Three	Three
Format	Liquid ready to use	Liquid ready to use
Fluid Matrix	Prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added.	Prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added.

5.9 Conclusions

The information presented in this premarket notification provide a reasonable assurance that the VITROS Chemistry Products Calibrator Kit 99 and the VITROS Chemistry Products AAT/HPT Performance Verifiers I, II and III are safe and effective for the stated intended uses.

Ortho-Clinical Diagnostics, Inc. believes that the VITROS Chemistry Products Calibrator Kit 99 (new intended use), and VITROS Chemistry Products AAT/HPT Performance Verifiers I, II, and III are substantially equivalent to the VITROS Chemistry Products Calibrator Kit 99 (current product), and VITROS Chemistry Products AAT Performance Verifiers I, II, and III respectively. The predicate devices were both previously cleared by the FDA (K052819) for IVD use.



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Ortho-Clinical Diagnostics, Inc.
c/o Ms. Marlene Hanna
Regulatory Affairs Manager
100 Indigo Creek Dr.
Rochester, NY 14626-5101

Re: k060940

Trade/Device Name: VITROS Chemistry Products Calibrator Kit 99
VITROS Chemistry Products AAT/HPT Performance Verifier I, II and III
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX, JJX
Dated: April 5, 2006
Received: April 6, 2006

Dear Ms. Hanna:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

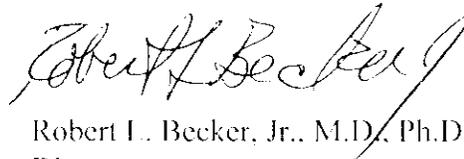
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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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 Compliance 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,

A handwritten signature in cursive script, reading "Robert L. Becker, Jr.", written in black ink.

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number
(if known): K060940

Device Name: VITROS Chemistry Products Calibrator Kit 99
VITROS Chemistry Products AAT/HPT Performance Verifier I, II, and III

Indications for Use: For *in vitro* diagnostic use only.
VITROS Chemistry Products Calibrator Kit 99 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of proteins in body fluids.

For *in vitro* diagnostic use only.
VITROS Chemistry Products AAT/HPT Performance Verifiers are assayed controls used to monitor the performance of protein measurements in body fluids on VITROS 5,1 FS Chemistry Systems.

Prescription Use 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 CDRII, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chen
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060940