JUN 15 2006

Ortho-Clinical Diagnostics
a Johnson & Johnson company

100 Indigo Creek Drive
Rochester, New York 14626-5101

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: K061464

1. **Submitter name, address, contact**

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Contact Person: Darlene J. Phillips

2. **Preparation date**

May 24, 2006

3. **Device name**

Trade or Proprietary Name:
VITROS Chemistry Products TIBC Kit
VITROS Chemistry Products Calibrator Kit 4

Common Name: TIBC test
Classification Name: Iron binding capacity test system (21 CFR 862.1415).

Common Name: Calibrator Kit 4
Classification Name: Calibrator (21 CFR 862.1150)

4. **Predicate device**

The VITROS TIBC assay (modified device) is substantially equivalent to the VITROS TIBC assay (original). This assay was originally cleared under the KODAK EKTACHEM product branding (K931493).

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5. Device description

The VITROS TIBC assay is performed using the VITROS Chemistry Products TIBC Kit, VITROS Chemistry Products Fe Slides, and the VITROS Chemistry Products Calibrator Kit 4 on VITROS Chemistry Systems.

The VITROS TIBC Kit consists of VITROS TIBC Columns (containing alumina) and VITROS Iron Saturating Reagent.

Total iron-binding capacity is determined by pretreating a sample using the method of Starr.[1] Excess iron citrate reagent is added to the sample to saturate all available apotransferrin sites. After an incubation period of five minutes, the treated sample is applied to an alumina column where iron that is not bound to transferrin is adsorbed.

The transferrin-bound iron contained in the eluate represents the total iron-binding capacity of the sample.

A drop of eluate is deposited on the VITROS Fe Slide and is evenly distributed by the spreading layer to the underlying layers. After the addition of the eluate, the slide is incubated at 37°C. Two reflection density measurements at 600 nm are made at approximately one and five minutes. The difference in reflection density is proportional to the iron concentration in the sample.

Once a calibration has been performed for each slide lot, total iron binding capacity in unknown samples can be determined using the software-resident two-point rate math model and the change in reflectance calculated for each unknown test slide.

VITROS Calibrator Kit 4 contains four levels of lyophilized standards with corresponding diluents. The standards are prepared from processed bovine serum and bovine serum albumin to which organic analytes, inorganic salts, electrolytes, stabilizers, and preservatives have been added. The diluents are prepared from processed water. Once reconstituted, the standards are used to calibrate VITROS Chemistry Systems for the quantitative measurement of total iron binding capacity in serum. Calibration of the VITROS TIBC assay requires the use of three of the four levels (bottles 1, 3 and 4).

6. Device intended use

For *in vitro* diagnostic use only.
VITROS Chemistry Products TIBC Kit with VITROS Chemistry Products Fe Slides quantitatively measures total iron-binding capacity (TIBC) in serum.

For *in vitro* diagnostic use only.
VITROS Chemistry Products Calibrator Kit 4 is used in the calibration of the VITROS Chemistry Systems for the quantitative measurement of ALB, BuBc, Fe, TBIL, TIBC, and TP.

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7. Comparison to predicate device The VITROS TIBC assay (modified device) is substantially equivalent to the predicate, VITROS TIBC assay (original), which was cleared by the FDA (K931493) for *in vitro* diagnostic use.

Table 1 List of Assay Characteristics: Comparison to Predicate Device

Device Characteristic	Modified Device VITROS TIBC assay (modified)	Predicate Device VITROS TIBC assay (original)
Intended Use	No change	For *in vitro* diagnostic use only. VITROS Chemistry Products TIBC Kit with VITROS Chemistry Products Fe Slides quantitatively measures total iron-binding capacity (TIBC) in serum. VITROS Chemistry Products Calibrator Kit 4 is used in the calibration of VITROS Chemistry Systems for the quantitative measurement of ALB, BuBc, Fe, TBIL, TIBC, and TP.
Calibration traceability	Traceable to SRM 937 via NCCLS approved standard method as defined in NCCLS document H17-A[2].	Traceable to SRM 937 via NCCLS proposed standard method as defined in NCCLS document H17-P[3] modified according to ICSH.
Manufacturer's Selected Measurement Procedure	The approved method for determination of serum iron, total iron binding capacity and percent transferrin saturation, NCCLS document H17-A[2] using ferene dye. The H17-A method incorporates the use of magnesium carbonate ($MgCO_3$) as the chelating agent for excess Fe^{+3}.	The proposed method for determination of iron and total iron binding capacity, NCCLS document H17-P[3], modified according to the International Committee for Standardization in Hematology (ICSH) recommendation to use ferene dye[4]. The modified H17-P method incorporates the application of alumina as the chelating agent for excess Fe^{+3}.
Reference Interval	Males: 261 – 462 µg/dL Females: 265 – 497 µg/dL	250 – 450 µg/dL
Reportable range	85 - 650 µg/dL	6 – 650 µg/dL
Sample type	No change	Serum
Basic principle	No change	Two point colorimetric rate
Instrumentation	No change	VITROS Chemistry Systems

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8.Conclusions

The information presented in the pre-market notification demonstrates that the performance of the VITROS TIBC assay (modified device) for use with human serum is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured reagents along with quality control fluids, proficiency samples and human serum samples with measured TIBC values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS TIBC assay (modified device) for use with human serum is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 15 2006

Darlene Phillips, RAC
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k061464
Trade/Device Name: VITROS Chemistry Products TIBC Kit
VITROS Chemistry Products Calibrator Kit 4
Regulation Number: 21 CFR§862.1415
Regulation Name: Iron-binding capacity test system
Regulatory Class: Class II
Product Code: JMO, JIX
Dated: May 24, 2006
Received: May 25, 2006

Dear Ms. Phillips:

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,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061464

Device Name: VITROS Chemistry Products TIBC Kit
VITROS Chemistry Products Calibrator Kit 4

Indications for Use: For *in vitro* diagnostic use only.
VITROS Chemistry Products TIBC Kit with VITROS Chemistry Products Fe Slides quantitatively measures total iron-binding capacity (TIBC) in serum. The iron binding capacity is useful in the differential diagnosis of anemia, iron deficiency anemia, thalassemia, sideroblastic anemia, and iron poisoning.

VITROS Chemistry Products Calibrator Kit 4 is used to calibrate VITROS Chemistry Systems for the quantitative measurement of ALB, BuBc, Fe, TBIL, TIBC, and TP.

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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061464