JUN 17 2004

Section 1: Summary Information

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: K041327

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

Ortho-Clinical Diagnostics, Inc.
Mail Stop 881
100 Indigo Creek Drive
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(585) 453-4253

Contact Person: Sarah CV Parsons, RAC

2. **Preparation date**

Date Special 510(k) prepared: May 17, 2004

3. **Device name**

Trade or Proprietary Name:
VITROS Immunodiagnostic Products CEA Reagent Pack
VITROS Immunodiagnostic Products CEA Calibrator
VITROS Immunodiagnostic Products CEA Range Verifiers

Common Name : VITROS CEA assay
Classification Name: Tumor associated antigen immunological test system (21 CFR 866.6010).

4. **Predicate device**

The VITROS Immunodiagnostic Products CEA Reagent Pack, VITROS Immunodiagnostic Products CEA Calibrators (new formulation) and VITROS Immunodiagnostic Products CEA Range Verifiers (new formulation) are substantially equivalent to the VITROS Immunodiagnostic Products CEA Reagent Pack and VITROS Immunodiagnostic Products CEA Calibrators (original formulation) and VITROS Immunodiagnostic Products CEA Range Verifiers (original formulation).

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5. Device description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

- The VITROS Immunodiagnostic Products range of immunoassay products (in this case VITROS Immunodiagnostic Products CEA Reagent Pack, VITROS Immunodiagnostic Products CEA Calibrators (both cleared under K990943), and VITROS Immunodiagnostic Products CEA Range Verifiers (K990984) which are combined by the VITROS Immunodiagnostic System to perform the VITROS CEA assay.

- The VITROS Immunodiagnostic System – instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

- Common reagents used by the VITROS System in each assay include the VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent which were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

The VITROS System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

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6. Device intended use

VITROS Immunodiagnostic Products CEA Reagent Pack
For *in vitro* diagnostic use only.
The VITROS CEA Reagent Pack quantitatively measures carcinoembryonic antigen (CEA) concentration in human serum and plasma to aid in the prognosis and management of caner patients in whom changing concentrations of CEA are observed.

VITROS Immunodiagnostic Products CEA Calibrators
For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of CEA in serum and plasma (EDTA or heparin).

VITROS Immunodiagnostic Products CEA Range Verifiers
For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of CEA.

7. Comparison to predicate device

The VITROS Immunodiagnostic Products CEA Reagent Pack, the VITROS Immunodiagnostic Products CEA Calibrators (new formulation) and the VITROS Immunodiagnostic Products CEA Range Verifiers (new formulation) are substantially equivalent to VITROS Immunodiagnostic Products CEA Reagent Pack and VITROS Immunodiagnostic Products CEA Calibrators (K990943) and VITROS Immunodiagnostic Products CEA Range Verifiers (K990984) cleared by the FDA for *in vitro* diagnostic use.

Table 1 lists the characteristics of the VITROS CEA assay (new formulation) and the VITROS CEA Assay (original formulation).

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Table 1 List of Assay Characteristics: Comparison to Predicate Device

Device Characteristic	Predicate Device VITROS CEA assay (Current)	New Device VITROS CEA assay (Modified)
Number of Calibrators	**3**	**2**
Nominal Calibrator values	**0, 5** and 250 ng/mL	**3** & 250 ng/mL
Calibration range	0 to 400 ng/mL	0 to 400 ng/mL
Sample type	Serum and plasma (EDTA or heparin).	Serum and plasma (EDTA or heparin).
Antibody	Mouse monoclonal anti-CEA antibody in biotinylated antibody reagent	Mouse monoclonal anti-CEA antibody in biotinylated antibody reagent
Base Matrix: Calibrators and Range Verifiers	**Liquid BSA**	**New Born Calf Serum**
Preservative: Calibrators and Range Verifiers	**Proclin**	**Kathon**
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Instrumentation	VITROS Immunodiagnostic System	VITROS Immunodiagnostic System
Sample volume	20µL	20µL
Incubation time and temperature	30 minutes at 37°C	30 minutes at 37°C

8. Conclusions The information presented in the pre-market notification demonstrates that the performance of the VITROS Immunodiagnostic Products CEA assay (new formulation) is substantially equivalent to the cleared predicate device.

Equivalent performance was demonstrated using manufactured reagents, positive and negative controls and testing human samples near the low end of the assay range.

The information presented in the premarket notification provide a reasonable assurance that the VITROS CEA Assay is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sarah Parsons, RAC
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Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

JUN 17 2004

Re: k041322
Trade/Device Name: VITROS Immunodiagnostic Products CEA Reagent Pack
VITROS Immunodiagnostic Products CEA Calibrators
VITROS Immunodiagnostic Products CEA Range Verifiers
Regulation Number: 21 CFR § 866.6010
Regulation Name: Carcinoembryonic Antigen (CEA) Immunological Test System
Regulatory Class: II
Product Code: DHX, JJX
Dated: May 17, 2004
Received: May 18, 2004

Dear Ms. Parsons:

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). 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/dsma/dsmamain.html.

Sincerely yours,

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

Statement of Intended Use

510(k) Number (if known): K041322

Device Name:

VITROS Immunodiagnostic Products CEA Reagent Pack
VITROS Immunodiagnostic Products CEA Calibrators
VITROS Immunodiagnostic Products CEA Range Verifiers

Indications for Use:

VITROS Immunodiagnostic Products CEA Reagent Pack
For *in vitro* diagnostic use only.
The VITROS CEA Reagent Pack quantitatively measures carcinoembryonic antigen (CEA) concentration in human serum and plasma to aid in the prognosis and management of cancer patients in whom changing concentrations of CEA are observed.

VITROS Immunodiagnostic Products CEA Calibrators
For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of CEA in serum and plasma (EDTA or heparin).

VITROS Immunodiagnostic Products CEA Range Verifiers
For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of CEA.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21CFR807 Subpart C)
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert A. Becker

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety