MAR 1 8 2003

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: K030626

1.	**Submitter Name, Address, Contact**	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (585) 453-4253 Contact Person: Darlene J. Phillips
2.	**Preparation Date**	Date Special 510(k) prepared: 25 February2003
3.	**Device name**	Trade or Proprietary Name: *Vitros* Chemistry Products CRP Slides Common Name: CRP test Classification Name: C-reactive protein immunological test system (21 CFR 866.5270)
4.	**Predicate**	The *Vitros* Chemistry Products CRP Slides (modified) and *Vitros* Chemistry Products Calibrator Kit 7 are substantially equivalent to the *Vitros* Chemistry Products CRP Slides (current slide) and *Vitros* Chemistry Products Calibrator Kit 7.

Continued on next page

5. Device description

The *Vitros* Chemistry System uses *Vitros* Slides to perform discrete chemistry tests on body fluid specimens. All reactions necessary for a single quantitative measurement take place within the multilayered analytical element of a *Vitros* slide.

The system is comprised of two main elements:

1. The range of *Vitros* Chemistry Products (in this case *Vitros* Chemistry Products CRP Slides and *Vitros* Chemistry Products Calibrator Kit 7), which are combined on the *Vitros* Chemistry System to perform the *Vitros* CRP assay.

2. The *Vitros* Chemistry System – instrumentation, which provides automated use of the chemistry slides. *Vitros* 250 and 950 Chemistry Systems were cleared for market by separate 510(k) pre-market notifications (K922072 and K946090, respectively).

The *Vitros* Chemistry System and Calibrators are dedicated specifically for use only with the *Vitros* Chemistry Products range of products.

The *Vitros* System uses common reagents. The *Vitros* Chemistry Products Specialty Diluent and *Vitros* ImmunoWash fluid were cleared by previous 510(k) pre-market notification (K962235 and K942610, respectively).

6. Device intended use

Vitros Chemistry Products CRP Slides
For *in vitro* diagnostic use only.
Vitros Chemistry Products CRP Slides quantitatively measure C-reactive protein (CRP) concentration in serum and plasma.

Vitros Chemistry Products Calibrator Kit 7
For *in vitro* diagnostic use only.
Vitros Calibrator Kit 7 is intended for use in the calibration of the *Vitros* Chemistry Systems for the quantitative measurement of CRP.

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7. Comparison to predicate device

The *Vitros* Chemistry Products CRP Slides (modified) and *Vitros* Chemistry Products Calibrator Kit 7 are substantially equivalent to *Vitros* Chemistry Products CRP Slides (current) and *Vitros* Chemistry Products Calibrator Kit 7 which were cleared by the FDA for *in vitro* diagnostic use with human serum and plasma. (K953197, cleared July 31, 1995)

Table 1 lists the characteristics of the tests performed using the *Vitros* Chemistry Products CRP Slides (modified) and *Vitros* Chemistry Products CRP Slides (current slide).

Table 1 List of Assay Characteristics: Comparison to Predicate Device

Device Characteristic	New Device *Vitros* CRP Slide (Modified)	Predicate Device *Vitros* CRP Slide (Current)
Sample Volume	No Change.	11 µL
Wash volume	No change	12 µL
Intended Use	No Change.	For in vitro diagnostic use only. *Vitros* CRP Slides quantitatively measure C-reactive protein (CRP) concentration in serum and plasma.
Basic Principle	No Change.	Dry multi-layered slide utilizing reflectance spectrophotometry.
Sample Type	Serum Plasma (heparin and EDTA)	Serum Plasma (lithium heparin, sodium citrate and EDTA)
Reportable Range Serum, Plasma	0.3 – 11.0 mg/dL (Conv. Units) 3 – 110 mg/L (SI Units) 300 – 11000 µg/dL (Alt. Units)	0.7 – 110.0 mg/dL (Conv. Units) 7 – 110 mg/L (SI Units) 700 – 11000 µg/dL (Alt. Units)
Instrumentation	No Change.	*Vitros* 250 and 950 Chemistry Systems
Incubation time and temperature	No Change.	7.5 minutes at 37°C
Slide Reactive Ingredients per cm^2:		
Immobilized phosphorylcholine	No change	0.07 mg
Anti-CRP antibody labeled with HRP	0.0006 units	0.0009 units
Calcium chloride	0.08 mg	0.10 mg
Leuco dye	No change	0.04 mg

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8. Conclusion

The information presented in the pre-market notification demonstrate that the performance of the *Vitros* Chemistry Products CRP Slides (modified) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured CRP values spanning the reportable range.

The information presented in the premarket notification provide a reasonable assurance that the *Vitros* Chemistry Products CRP Slides (modified) is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 8 2003

Ms. Darlene J. Phillips
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: k030626
Trade/Device Name: VITROS Chemistry Products CRP Slide and
VITROS Chemistry Products Calibrator Kit 7
Regulation Number: 21 CFR § 866.5270
Regulation Name: C-reactive protein immunological test systems
Regulatory Class: II
Product Code: DCK, JIT
Dated: February 25, 2003
Received: February 27, 2003

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 (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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
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): K030626

Device Name:

Vitros Chemistry Products CRP Slides
Vitros Chemistry Products Calibrator Kit 7

Intended Use:

Vitros Chemistry Products CRP Slides
For *in vitro* diagnostic use only.
Vitros Chemistry Products CRP Slides quantitatively measure C-reactive protein (CRP) concentration in serum and plasma.

Vitros Chemistry Products Calibrator Kit 7
For *in vitro* diagnostic use only.
Vitros Calibrator Kit 7 is intended for use in the calibration of the *Vitros* Chemistry Systems for the quantitative measurement of CRP.

Summary and Explanation of Test

C-reactive protein is synthesized by the liver and is one of the acute phase proteins. In the acute phase response, increased concentrations of a number of plasma proteins, including CRP, are observed.[1]
CRP concentration measurements are useful in the detection and evaluation of inflammatory disorders, tissue injury, and infections.[2, 3]

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J. P Reeves for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030626

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)