



Food and Drug Administration
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ORTHO-CLINICAL DIAGNOSTICS, INC.
MS. JESSICA MILLER
SENIOR REGULATORY AFFAIRS ASSOCIATE
100 INDIGO CREEK DRIVE
ROCHESTER, NEW YORK 14626

Re: K152433

Trade/Device Name: VITROS Chemistry Products CRP Slides
VITROS Chemistry Products Calibrator Kit 7
Regulation Number: 21 CFR 866.5270
Regulation Name: C-Reactive Protein immunological test system
Regulatory Class: II
Product Code: DCK, JIT
Dated: August 26, 2015
Received: August 27, 2015

Dear Ms. Miller:

September 24, 2015

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kelly Oliner -S

FOR

Leonthena Carrington, MS, MBA, MT (ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152433

Device Name

VITROS Chemistry Products CRP Slides and VITROS Chemistry Products Calibrator Kit 7

Indications for Use (Describe)

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 using VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.

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. CRP concentration measurements are useful in the detection and evaluation of inflammatory disorders, tissue injury, and infections.

VITROS Chemistry Products Calibrator Kit 7:

For in vitro diagnostic use only.

VITROS Chemistry Products Calibrator Kit 7 is used to calibrate VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of CRP.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

VITROS Chemistry Products CRP Slides, Calibrator Kit 7

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Ortho-Clinical Diagnostics, Inc.
Address	100 Indigo Creek Drive Rochester, New York 14626
Phone number	908-218-8173
Fax number	908-218-8168
Establishment Registration Number	1319681
Name of contact person	Jessica Miller
Date prepared	August 26, 2015
Name of devices	
Trade or proprietary name	VITROS Chemistry Products CRP Slides VITROS Chemistry Products Calibrator Kit 7
Common or usual name	C-reactive protein immunological test system
Classification name	C-reactive protein, antigen, antiserum, and control
Classification panel	Immunology
Regulation	21 CFR 866.5270: C-Reactive Protein immunological test system 21 CFR 862.1150: Calibrator Classification: Class II
Product Code(s)	DCK, JIT
Legally marketed device(s) to which equivalence is claimed	The VITROS Chemistry Products CRP Slides and VITROS Chemistry Products Calibrator Kit 7 (modified) is substantially equivalent to the VITROS Chemistry Products CRP Slides and VITROS Chemistry Products Calibrator Kit 7 (current), cleared March, 2003 (K030626).

<p>Device description</p>	<p>The VITROS CRP Slide method is performed using the VITROS CRP Slides and the VITROS Chemistry Products Calibrator Kit 7 on VITROS Chemistry and Integrated Systems.</p> <p>The VITROS CRP Slide is a multilayered, analytical element coated on a polyester support. The immuno-rate format for CRP is based on an enzymatic heterogeneous, sandwich immunoassay format. In this format a derivative of phosphorylcholine (PC) is covalently bound to polystyrene polymer beads and in the presence of calcium serves as a capture agent. Monoclonal anti-CRP antibody conjugated to horseradish peroxidase (HRP) serves as a signal generator. A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. CRP in the sample binds to PC-linked capture beads and anti-CRP antibody labeled with horseradish peroxidase to form an insoluble sandwich complex in Incubation 1. The subsequent addition of 12 μL of VITROS Immuno-Wash Fluid to the slide removes unbound materials from the read area, while also providing the hydrogen peroxide required for the enzyme-mediated oxidation of leuco dye.</p> <p>The reflection density of the dye is measured after the addition of VITROS Immuno-Wash Fluid at the end of Incubation 2. This reflection density is directly proportional to the concentration of CRP in the sample. To determine if an adequate wash has occurred, the wash detection dye is read at 540 nm immediately after Incubation 2.</p> <p>The VITROS Calibrator Kit 7 is prepared from processed human serum to which purified human C-reactive protein, inorganic salts, and preservatives have been added. The human blood products provided as components of VITROS Calibrator Kit 7 have been tested at the individual donor level and found nonreactive for hepatitis B surface antigen (HBsAg), antibody to HCV, and antibody to HIV using FDA approved methods.</p>
<p>Intended Use/Indications for Use</p>	<p><u>CRP Slide:</u> For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products CRP Slides quantitatively measure C-reactive protein (CRP) concentration in serum and plasma using VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.</p>

	<p>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. CRP concentration measurements are useful in the detection and evaluation of inflammatory disorders, tissue injury, and infections.</p> <p><u>Calibrator Kit 7:</u> For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Calibrator Kit 7 is used to calibrate VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of CRP.</p>
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Comparison with Predicate Devices:

Table 1: VITROS Chemistry Products CRP Slides

Characteristic	Predicate [VITROS CRP Slides (Current), K030626]	New Device [VITROS CRP Slides (Modified)]
Intended Use	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products CRP Slides quantitatively measure C-reactive protein (CRP) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products CRP Slides quantitatively measure C-reactive protein (CRP) concentration in serum and plasma using VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.
Basic Principle	Fixed-point immuno-rate	No Change

Table 1: VITROS Chemistry Products CRP Slides

Characteristic	Predicate [VITROS CRP Slides (Current), K030626]	New Device [VITROS CRP Slides (Modified)]
Reagent Composition	<p>Reactive Ingredients: Immobilized phosphorylcholine; mouse anti-CRP antibody labeled with horseradish peroxidase; calcium chloride; and 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl)imidazole (leuco dye)</p> <p>Other Ingredients: Binders, buffer, surfactants, cross-linking agent, polymer beads, proteins, stabilizers and wash detection dye.</p>	No Change
Sample volume	11 µL	No Change
Sample type	Serum, plasma	No Change
Assay Range Serum, Plasma	5 - 90 mg/L	No Change
Incubation time and temperature	7.5 minutes at 37°C	No Change
Calibration Traceability of Values (VITROS Chemistry Products Calibrator Kit 7)	IRMM Reference Material ERM-DA472	IRMM Reference Material ERM-DA474/IFCC

Table 2: VITROS Chemistry Products Calibrator Kit 7

Characteristic	Predicate [VITROS Calibrator Kit 7 (Current), K030626]	New Device [VITROS Calibrator Kit 7 (Modified)]
Intended Use	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Calibrator Kit 7 is used to calibrate VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of CRP.	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Calibrator Kit 7 is used to calibrate VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of CRP.
Matrix/Ingredients	Liquid; processed human serum to which purified human C-reactive protein, inorganic salts, and preservatives have been added.	No Change
Traceability of Values	IRMM Reference Material ERM-DA472	IRMM Reference Material ERM-DA474/IFCC
Nominal Values for CRP	Vial 1: 7 mg/L Vial 2: 25 mg/L Vial 3: 100 mg/L	No Change

Performance Summary:

Substantial Equivalence was demonstrated by testing several performance characteristics including method comparison, linearity and detection (analytical range).

Method Comparison:

Method Comparison testing followed CLSI Protocol EP09-A3, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples*. Human serum samples were tested with the VITROS Chemistry Products CRP assay traceable to ERM-DA474 and the obtained results were compared to the predicate method (VITROS Chemistry Products CRP assay traceable to ERM-DA472). 98 to 103 samples ranging from 5 to 90 mg/L were tested with both assays. The correlation between the assays on each VITROS System is summarized below.

Analyzer	Parameter	Result
VITROS 350 Chemistry System	Slope (95% CI)	1.009 (1.008 to 1.010)
	y-intercept (95% CI)	-4.819 (4.886 to -4.751)
VITROS 5,1 FS Chemistry System	Slope (95% CI)	1.009 (1.007 to 1.011)
	y-intercept (95% CI)	-4.938 (-5.070 to -4.805)
VITROS 4600 Chemistry System	Slope (95% CI)	1.009 (1.006 to 1.012)
	y-intercept (95% CI)	-4.952 (-5.114 to -4.790)
VITROS 5600 Chemistry System	Slope (95% CI)	1.009 (1.006 to 1.011)
	y-intercept (95% CI)	-4.905 (-5.052 to -4.759)

Limits of blank, detection, and quantitation:

The Limit of Blank (LOB), Limit of Detection (LOD), and Limit of Quantitation (LOQ) of the VITROS CRP assay were determined according to CLSI EP17-A2: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures*. The following limits were determined:

LOB: 2.03 mg/L

LOD: 2.72 mg/L

LOQ: 4.80 mg/L

Linearity:

Linearity was determined following CLSI EP6-A: *Evaluation of the Linearity of Quantitative Measurement Procedures: a Statistical Approach: Approved Guideline*. A high CRP serum pool was intermixed with a low serum pool to generate 14 concentration levels each tested in six replicate determinations. Linear results were compared to 2nd and 3rd order polynomial fits against a pre-specified allowable error. The linearity range was found to extend across the measuring range of 5 to 90 mg/L.

Analytical Range (Serum/Plasma):

Results from linearity and detection studies support the analytical measuring range of the VITROS Chemistry Products Slides on the VITROS Systems as seen below.

Analyzers	VITROS Chemistry Products CRP Assay
VITROS 250/350, 5,1 FS, and 4600 Chemistry System, VITROS 5600 Integrated System	5 to 90 mg/L

Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate the modified VITROS Chemistry Products CRP Slides and VITROS Chemistry Products Calibrator Kit 7 are as safe and effective as the predicate devices. The information submitted in the premarket notification is complete and supports a substantial equivalence decision.