### 510(k) SUMMARY

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

<table>
<thead>
<tr>
<th>Submitter Information</th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
<td>Ortho-Clinical Diagnostics, Inc.</td>
</tr>
</tbody>
</table>
| **Address** | 100 Indigo Creek Drive  
Rochester, New York 14626 |
| **Phone number** | (585) 453-3962 |
| **Fax number** | (585) 453-3368 |
| **Establishment Registration Number** | 1319809 |
| **Name of contact person** | Gaozhen Hang |
| **Date prepared** | February 8, 2013 |

<table>
<thead>
<tr>
<th>Name of device</th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Trade or proprietary name</strong></td>
<td>VITROS Chemistry Products TRIG Slides</td>
</tr>
<tr>
<td><strong>Common or usual name</strong></td>
<td>Lipase Hydrolysis/Glycerol Kinase Enzyme, Triglycerides</td>
</tr>
<tr>
<td><strong>Classification name</strong></td>
<td>Triglyceride test system</td>
</tr>
<tr>
<td><strong>Classification panel</strong></td>
<td>Clinical Chemistry</td>
</tr>
<tr>
<td><strong>Regulation</strong></td>
<td>21 CFR 862.1705</td>
</tr>
<tr>
<td><strong>Product Code(s)</strong></td>
<td>CDT</td>
</tr>
<tr>
<td><strong>Legally marketed device(s) to which equivalence is claimed</strong></td>
<td>The VITROS Chemistry Products TRIG Slides (modified) are substantially equivalent to the VITROS Chemistry Products TRIG Slides (current). The FDA cleared the VITROS Chemistry Products TRIG Slides on August 3, 1981 (k812029).</td>
</tr>
</tbody>
</table>
**Reason for 510(k) submission**

A Special 510(k) for a modification to own device which does not include a change in intended use or fundamental technology. The biological source of lipase, one of the reactive ingredients used in VITROS Chemistry Products TRIG Slides, is being changing from the fungi *Candida rugosa* to the microorganism *Pseudomonas*. It enhances supply chain continuity. NOTE: The exact material (active ingredients-Lipase) has been used on this device type, so, per guidance, a special 510(k) can be used. The source of the active ingredient (Lipase, E.C. 3.1.1.3) changed from a from *Candida rugosa* to *Pseudomonas*; however, the lipase is the same material, has the same E.C. number, and has the same function as the lipase used in the current VITROS TRIG Slides for over 31 years.

**Device description**

The VITROS TRIG assay is performed using the VITROS Chemistry Products TRIG Slides and the VITROS Chemistry Products Calibrator Kit 2 on the VITROS Chemistry Systems. The VITROS TRIG Slide is a multi-layered, analytical element coated on a polyester support. The method is based on an enzymatic detection. All reactions necessary for a single quantitative measurement of triglyceride take place within the multi-layered analytical element of a VITROS Chemistry Products TRIG Slide. A drop of sample fluid is metered onto the slide and a reaction occurs which ultimately results in the oxidation of a leuco dye by hydrogen peroxide. The concentration of triglyceride in the sample is determined by measuring the absorbance of the dye by reflectance spectrophotometry.

**Intended use of the device**

For *in vitro* diagnostic use only. VITROS Chemistry Products TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma using VITROS® Systems.

**Indications for use**

For *in vitro* diagnostic use only. VITROS Chemistry Products TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma using VITROS® Systems. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>New Device [VITROS TRIG Slide (Modified)]</th>
<th>Predicate [VITROS TRIG Slide (Current)] [k812029]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>No Change</td>
<td>For <em>in vitro</em> diagnostic use only. VITROS Chemistry Products TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.</td>
</tr>
<tr>
<td>Basic Principle</td>
<td>No Change</td>
<td>Enzymatic Endpoint test type utilizing reflectance spectrophotometry</td>
</tr>
<tr>
<td>Concentrations of VITROS TRIG Slide Reactive Ingredients per cm-squared</td>
<td>Lipase (<em>Pseudomonas</em> E.C. 3.1.1.3) 0.08 U</td>
<td>Lipase (<em>Candida rugosa</em> E.C. 3.1.1.3) 0.15 U</td>
</tr>
<tr>
<td>Sample volume</td>
<td>No Change</td>
<td>Peroxidase (horseradish root E.C.1.11.1.7) 0.52 U; glycerol kinase (Cellulomonas sp., E.C.2.7.1.30) 0.35 U; L-α-glycerophosphate oxidase (<em>Pediococcus</em> sp., E.C.1.1.3.-) 0.19 U; Triton X-100 0.62 mg; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 0.04 mg; and adenosine triphosphate 0.14 mg.</td>
</tr>
<tr>
<td>Sample type</td>
<td>No Change</td>
<td>Serum, plasma</td>
</tr>
<tr>
<td>Assay Range Serum, Plasma</td>
<td>No Change</td>
<td>10.0-525.0 mg/dL</td>
</tr>
<tr>
<td>Incubation time and temperature</td>
<td>No Change</td>
<td>5 minutes at 37°C</td>
</tr>
</tbody>
</table>

Ortho-Clinical Diagnostics
VITROS® Chemistry Product TRIG Slides
Special 510(k)
### Summary of design control activities conducted in relation to the device modification

The Ortho-Clinical Diagnostics, Inc. procedure for risk management is based on ISO 14971, Medical Devices – Application of Risk Management to Medical Devices and references CDRH Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management.

The risk analysis method used to assess the impact of the device modification was a Hazard Analysis. The following performance characteristics: accuracy, precision, linearity, potential interferents, long term and on-analyzer stability, limit of detection and specimen type were considered for potential hazards. Validation and verification testing were conducted and the modified device met the pre-determined acceptance criteria for all the performance testing. The modification does not negatively impact the performance of the device or the safety and effectiveness of the device.

### CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The information presented in the premarket notification provides a reasonable assurance that the VITROS Chemistry Products TRIG Slides (modified) for use with human serum and plasma is substantially equivalent to the predicate (unmodified VITROS TRIG Slides) and is safe and effective for the stated intended use.

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Ortho-Clinical Diagnostics
VITROS® Chemistry Product TRIG Slides
Special 510(k)
May 31, 2013

Ortho-Clinical Diagnostics, Inc.
C/O Gaozhen Hang
100 Indigo Creek Drive
ROCHESTER NY 14626-5101

Re: K130332
Trade/Device Name: VITROS Chemistry Products TRIG Slide
Regulation Number: 21 CFR 862.1705
Regulation Name: Triglyceride test system
Regulatory Class: I, meets limitations of exemption per 21 CFR 862.9(c)(4)
Product Code: CDT
Dated: May 06, 2013
Received: May 09, 2013

Dear Gaozhen Hang:

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 Part 801); 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), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for
the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Carol Benson -S for

Courtney H. Lias, Ph.D.
Director,
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): k130332

Device Name: VITROS® Chemistry Products TRIG Slide

Indications for Use:

For in vitro diagnostic use only. VITROS Chemistry Products TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma using VITROS® Systems. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

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)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesley-S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130332