ORTHO-CLINICAL DIAGNOSTICS, INC.
BRADLEY P. BOYER
SENIOR REGULATORY ASSOCIATE
100 INDIGO CREEK DRIVE
ROCHESTER NY 14626

Re: K171168
Trade/Device Name: VITROS Immunodiagnostic Products Insulin Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: April 20, 2017
Received: April 21, 2017

Dear Bradley P. Boyer:

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 regulations (21 CFR Parts 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” (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 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,

Kellie B. Kelm -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

(Describe)

For in vitro diagnostic use only.

For use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System for the quantitative measurement of insulin in human serum and plasma (Li Heparin).

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Summary of Safety and Effectiveness for the
VITROS® Immunodiagnostic Products Insulin Calibrators

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.

1. 510(k) Number:
The assigned 510(k) number is: k171168

2. Applicant
   Contact Person: Bradley P. Boyer
   Senior Regulatory Associate
   Address: Ortho-Clinical Diagnostics, Inc.
   100 Indigo Creek Drive
   Rochester, New York 14626-5101
   Phone: (585) 453-3421
   Facsimile: (585) 453-3368
   Email: bradley.boyer@orthoclinicaldiagnostics.com

3. Date April 20, 2017

4. Device Name
   Trade or Proprietary Names:
   VITROS® Immunodiagnostic Products Insulin Calibrators
   Common Names:
   Insulin Calibrators

5. Regulatory Information
   Regulation section: 21 CFR 862.1150; calibrator, secondary
   Classification Class II
   Product Code: JIT
   Panel: Clinical Chemistry

6. Predicate Device
   Device Name Architect Insulin Calibrators
   510(k) number: K060359
   Manufacturer: Produced for Abbott by Denka Seiken Co., Ltd.

7. Intended Use
   See Indications for Use
8. **Indications for Use**

VITROS® Immunodiagnostic Products Insulin Calibrators

For *in vitro* diagnostic use only.

For use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System for the quantitative measurement of insulin in human serum and plasma (Li Heparin).

Special Conditions for use statement: For prescription use

9. **Device Description**

   **Calibrator description**

   The VITROS® Immunodiagnostic Products Insulin Calibrators contain three levels of calibrator, Calibrator 1, 2, 3. Nominal values are 1 µIU/mL, 25 µIU/mL and 250 µIU/mL respectively. The calibrators are liquid and comprised of recombinant human insulin in buffer containing BSA with an antimicrobial agent. VITROS® Immunodiagnostic Products Insulin Calibrators kit contains 1 vial of each calibrator 1, 2, and 3. Each vial contains 1mL of calibrator.

10. **Test Principle:**

    VITROS® Immunodiagnostic Products Insulin Calibrators are intended for *in vitro* diagnostic use in the calibration of the VITROS Immunodiagnostic Products Insulin test on VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System.

11. **Substantial Equivalence Information:**

    VITROS® Immunodiagnostic Products Insulin Calibrators are substantially equivalent to predicate device Architect Insulin Calibrators (k060359) which was cleared by FDA for IVD use.

    Comparison with predicate tables highlight similarities and differences, respectively, of the VITROS® Immunodiagnostic Products Insulin Calibrators as compared to the predicate device.
Comparison with Predicate - Similarities

<table>
<thead>
<tr>
<th>Device Characteristic</th>
<th>VITROS® Immunodiagnostic Products Insulin Calibrators (New device)</th>
<th>K060359 (Architect Insulin Calibrators)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>For use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System for the quantitative measurement of insulin in human serum and plasma (Li Heparin).</td>
<td>The Architect Insulin Calibrators are for the calibration of the Architect i System when used for the quantitative determination of human insulin in human serum or plasma</td>
</tr>
<tr>
<td>Measured Analyte</td>
<td>Insulin</td>
<td>same</td>
</tr>
<tr>
<td>Form</td>
<td>Liquid</td>
<td>same</td>
</tr>
<tr>
<td>Traceability</td>
<td>WHO 1st International Reference Preparation 66/304</td>
<td>same</td>
</tr>
<tr>
<td>Assay Protocol</td>
<td>Direct, quantitative immunoassay</td>
<td>same</td>
</tr>
</tbody>
</table>

Comparison with Predicate - Differences

<table>
<thead>
<tr>
<th>Device Characteristic</th>
<th>VITROS® Immunodiagnostic Products Insulin Calibrators (New device)</th>
<th>K060359 (Architect Insulin Calibrators)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrumentation</td>
<td>VITROS® ECi/ECiQ Immunodiagnostic Systems, VITROS® 3600 Immunodiagnostic System and the VITROS® 5600 Integrated System</td>
<td>Architect i System</td>
</tr>
<tr>
<td>Concentration / Levels</td>
<td>3 levels: 1, 25, 250 µIU/mL</td>
<td>Calibrators A-F. Cal A is acetate buffer, B-F are levels: 0, 3, 10, 30, 100 µU/mL</td>
</tr>
<tr>
<td>Matrix</td>
<td>Buffer containing BSA and antimicrobial agent</td>
<td>Acetate buffer with sodium azide and preservatives</td>
</tr>
<tr>
<td>Stability</td>
<td>Unopened Store at 2-8°C until expiration date Opened 13 weeks</td>
<td>Unopened Store at 2-8°C until expiration date Opened Store at 2-8°C until expiration date</td>
</tr>
</tbody>
</table>
The following recognized standard and guidance documents were used:

13. Performance Characteristics
The following studies are not applicable for the purpose of this submission:
   - Precision/Reproducibility
   - Linearity/Assay Reportable Range
   - Detection limit
   - Method and Matrix Comparison Studies
   - Analytical Specificity
   - Assay cut-off
   - Expected Values/Reference Interval

Summary of Stability
Shelf-life of the VITROS Immunodiagnostic Products Insulin Calibrators will be determined by a real time stability study. The stability study is designed to determine shelf-life for calibrators. The final shelf life claim will be based on the completed real time study results.

Storage life for open vials of VITROS Immunodiagnostic Products Insulin Calibrators will be determined by a real time stability study and will support the open off board shelf life statement in the Instructions for Use.

Summary of Traceability and Value assignment
Values assigned to the VITROS Immunodiagnostic Products Insulin Calibrators are traceable to the WHO 1st International Reference Preparation 66/304.

The Value assignment process transfers the calibration from the WHO Standard (66/304) to reference standards and then to calibrators used by the end user to establish a valid calibration curve on the VITROS ECi/ECiQ Immunodiagnostic Systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System.

14. Conclusion
Based on the comparison with the predicate device, the VITROS Immunodiagnostic Products Insulin Calibrators are substantially equivalent to the Architect Insulin Calibrators (k060359) cleared by FDA for IVD use.