DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 16, 2014

TOSOH BIOSCIENCE, INC.
ROBERT WICK
REGULATORY SPECIALIST
6000 SHORELINE COURT, STE. 101
SOUTH SAN FRANCISCO CA 94080

Re: K143296
Trade/Device Name: AIA-PACK C-Peptide Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: November 15, 2014
Received: November 17, 2014

Dear Mr. Robert Wick:

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,

Ruth A. Chesler -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143296

Device Name
AIA-PACK C-Peptide Control Set

Indications for Use *(Describe)*
The AIA-PACK C-Peptide Control Set is intended for In Vitro Diagnostic Use Only for performing quality control procedures with the ST AIA-PACK C-Peptide II assay.

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.

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

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510(k) Summary (k)143296

AIA-PACK C-Peptide Control Set

Date: December 16, 2014

Submitter:
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Grove City, OH 43123

Contact Person:
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Device Name: AIA-PACK C-Peptide Control Set

Classification:
Class I, reserved
JJX
Clinical Chemistry
21 CFR 862.1660

Predicate Device:
K111335
Tosoh Bioscience, Inc.
ST AIA-PACK ACTH (Control Set)

510(k) Summary

AIA-PACK C-Peptide Control Set

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Device Description:

2 x 2 mL AIA-PACK C-Peptide Control Level 1
Buffered bovine serum albumin containing approximately 2 ng/mL of C-peptide (Lyophilized). See the vial label for the assigned concentration range.
2 x 2 mL AIA-PACK C-Peptide Control Level 2
Buffered bovine serum albumin containing approximately 20 ng/mL of C-peptide (Lyophilized). See the vial label for the assigned concentration range.

AIA-PACK C-Peptide Control Set P/N # 025484

The AIA-PACK C-Peptide Control Set contains buffered bovine serum albumin with assigned levels of C-peptide. The C-peptide controls shall be run at the beginning of each day on which C-peptide assays are scheduled.

Device Intended Use:

The AIA-PACK C-Peptide Control Set is intended for In Vitro Diagnostic Use Only for performing quality control procedures with the ST AIA-PACK C-Peptide II assay.

Substantial Equivalence:

Comparison between the Tosoh AIA-PACK C-Peptide Control Set and the Tosoh AIA-PACK ACTH Control Set

Similarities

Control Set

Parameter	Tosoh AIA-PACK C-Peptide Control Set	Tosoh AIA-PACK ACTH Control Set (K111335)
Intended use	The AIA-PACK C-Peptide Control Set is intended for In Vitro Diagnostic Use Only for performing quality control procedures with the ST AIA-PACK C-Peptide II assay.	The AIA-PACK ACTH Control Set is intended for In Vitro Diagnostic Use Only for performing quality control procedures with the ST AIA-PACK ACTH Assay.
Number of levels	2	2
Matrix	Buffered bovine serum albumin	Buffered bovine serum albumin
Format	Lyophilized	Lyophilized

Differences

Control Set

Parameter	Tosoh AIA-PACK C-Peptide Control Set	Tosoh AIA-PACK ACTH Control Set (K111335)
Controls Concentrations	Two levels at approximately 2 and 20 ng/mL of C-Peptide	Two levels at approximately 50 and 300 pg/mL of ACTH

Traceability

Control materials were prepared from C-Peptide which was obtained from BACHEM, Product code: H-2470.1000.

Summary of Stability Studies

Three different lots of AIA-PACK C-Peptide Control Set were used as samples for the study. The study was initiated within one month from manufacture of the evaluated reagents, and then assayed at 6, 12 and 13 months after the day of the first assay. The criterion for recovery was within 100 +/- 10%. The criterion for reproducibility (CV %) was </= 10%. The recovery was within 100 +/- 10% and the reproducibility (CV %) was </=10% at 13 months, the shelf life of the ST AIA-PACK C-Peptide Control Set was set at 12 months at 2-8° C from the date of manufacturing.

The in use stability study for the ST AIA-PACK C-Peptide Control Set was conducted at one site using one AIA-2000 analyzer and a single lot of control set. The control set material were opened and reconstituted at day 0, 7, 8, 14 and 15 before the measurement. The reconstituted control set vials were sealed and refrigerated. Each specimen was assayed in 5 replicates. The criterion for recovery was 100 +/- 10%. The criterion for reproducibility (% CV) was </= 10%. Since the recovery and the reproducibility meet the acceptance criteria for 15 days at refrigerator temperature, the in use stability of the ST AIA-PACK C-Peptide Control Set after reconstitution, was set as 14 days.

When stored unopened and refrigerated at 2-8 °C, the Control Set is stable until the expiration date on the label. The controls should be used within 14 day of opening or reconstituting, provided the vials are kept tightly sealed and refrigerated at 2-8 °C.

Summary of Value Assignment

The primary reference material was prepared by diluting the C-peptide (purchased) with calibrator base and its value of C-peptide as reference material was assigned based on C-Peptide of Human Insulin, International Reference Reagent (WHO International Reference Regent) using ST AIA-PACK C-Peptide II. The value of the secondary reference material was assigned using the AIA 2000 instruments with the primary reference material as calibrator. The value was verified by comparing measured results with those obtained with the previous lot for patient samples or control materials.

The AIA-PACK C-Peptide Control Set values were assigned using the AIA 2000 instruments with the secondary reference material as calibrator. The Control set contains assigned concentration range of C-peptide. The assigned range is determined on a lot-by-lot basis and is designed to provide target control levels of approximately 2 and 20 ng/mL of C-peptide. The value assignment for the AIA-PACK C-Peptide Control was carried out using two AIA 2000 analyzers and 2 lots for control levels 1 and 2. Measurements were made in 5 replicates and mean values fell within the value range. In addition, all CV% fell within pre-determined acceptance criteria. The assigned control value range is +/- 20% of the target value for the AIA-PACK C-Peptide Control Set.

Conclusion:

The Tosoh Bioscience, Inc, AIA-PACK C-Peptide Control Set is substantially equivalent to the Tosoh Bioscience, Inc. AIA-PACK ACTH Control Set in
(k) 111335 with similar intended use.