DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

December 18, 2015

Re: K153417
Trade/Device Name: ST AIA-PACK PROG III Calibrator Set
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: November 24, 2015
Received: November 25, 2015

Dear 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,

Katherine Serrano -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)*
K153417

Device Name
ST AIA-PACK PROG III Calibrator Set

Indications for Use *(Describe)*
The ST AIA-PACK PROG III Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK PROG III 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.

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

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510(k) Summary
ST AIA-PACK PROG III Calibrator Set

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92

This Summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92.

2. SUBMITTER NAME AND ADDRESS

Date of Summary Preparation:	November 23, 2015
Submitter:	Tosoh Bioscience, Inc 3600 Gantz Road Grove City, OH 43123
Contact Person:	Robert L. Wick Regulatory Specialist 6000 Shoreline Ct., Ste. 101 South San Francisco, CA 94080 Phone: 650-636-8117 Fax: 650-636-8121 Email: Robert.Wick@Tosoh.com

3. 510K NUMBER, DEVICE PROPRIETARY NAME, COMMON NAME, PURPOSE FOR THE SUBMISSION, REGULATORY CLASSIFICATION, PANEL, PRODUCT CODE, AND 21 CFR NUMBER.

510k No.:	
Device Proprietary Name:	ST AIA-PACK PROG III Calibrator Set
Purpose of Submission:	New Product
Regulatory Classification	Calibrator, Secondary
Common Name:	Progesterone Test System
Classification:	Class II
Product Code:	JIT
Panel:	Clinical Chemistry
21 CFR Number:	21 CFR 862.1150

4. PREDICATE DEVICE PROPRIETARY NAMES AND 510 (K) NUMBERS

Predicate Device Number:	K933269
Predicate:	ST AIA-PACK PROG (Calibrator Set)
Manufacturer:	Tosoh Bioscience, Inc. (previously known as Tosoh Medics, Inc.)

5. INTENDED USE

The ST AIA-PACK PROG III Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK PROG III assay.

6. DEVICE DESCRIPTION

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 1 mL ST AIA-PACK PROG III Calibrator (1)	0	ng/mL
Bovine protein matrix containing no detectable concentration of progesterone with sodium azide as a preservative (Liquid).		
2 x 1 mL ST AIA-PACK PROG III Calibrator (2)	0.5	ng/mL (approx.)
ST AIA-PACK PROG III Calibrator (3)	1.5	ng/mL (approx.)
ST AIA-PACK PROG III Calibrator (4)	5.0	ng/mL (approx.)
ST AIA-PACK PROG III Calibrator (5)	15	ng/mL (approx.)
ST AIA-PACK PROG III Calibrator (6)	45	ng/mL (approx.)
Bovine protein matrix containing the assigned concentration of progesterone (described on each vial) with sodium azide as a preservative.		

ST AIA-PACK PROG III Calibrator Set P/N # 025340

The ST AIA-PACK PROG III Calibrator Set is designed specifically for use on the Tosoh AIA System Analyzers which have been previously cleared as a family of instruments under K971103. Only materials obtained from Tosoh should be used. Materials obtained elsewhere should not be substituted since assay performance is characterized based strictly on Tosoh materials.

The ST AIA-PACK PROG III Calibrator Set is designed for use with ST AIA-PACK PROG III and ST AIA-PACK PROG III Sample Diluting Solution.

7. PREDICATE COMPARISON TABLE

Substantial Equivalence:

Comparison between the Tosoh ST AIA-PACK PROG III Calibrator Set and the Tosoh ST AIA-PACK PROG Calibrator Set

Similarities

Characteristic	**Tosoh AIA-PACK PROG III Calibrator Set**	**Predicate** **Tosoh AIA-PACK PROG Calibrator Set (K933269)**
Intended Use	The ST AIA-PACK PROG III Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK PROG III assay.	The AIA-PACK PROG Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK PROG Assays.
Indications for Use (same as Intended Use)	The ST AIA-PACK PROG III Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK PROG III assay.	The AIA-PACK PROG Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK PROG Assays.
Analyte	Progesterone	Same
Format	Liquid Six bottles, one for each of the six calibrator levels.	Same
Matrix	Serum and heparinized plasma	Same
Storage	Store upright and refrigerate at 2 to 8°C.	Same
Stability (unopened vial)	Stable until the expiration date stated on the label when stored at 2 - 8°C.	Same
Calibration Stability	Stable up to 90 days	Same
Stability (opened vial)	24 hours (1 day)	Same

Differences

Characteristic	Tosoh AIA-PACK PROG III Calibrator Set	Predicate Tosoh AIA-PACK PROG Calibrator Set (K933269)
Shelf-life	8 months when stored unopened and refrigerated at 2-8°C	12 months when stored unopened and refrigerated at 2-8°C
Traceability	USP (United States Pharmacopeia) Standard (Lot #I1J239).	Internal reference standards.
Base	Bovine serum	Human serum
Levels	Six (0, 0.5, 1.5, 5.0, 15, 45 ng/mL approximately)	Six (0, 0.5, 1.5, 5.0, 20, 60 ng/mL approximately)
Analyzer	Tosoh AIA-2000	Tosoh AIA-1200

8. SUMMARY OF STABILITY STUDIES

Summary of Stability Studies

Real Time Testing

ST AIA-PACK Progesterone III Calibrator Set were stored at refrigerated temperatures and assayed at 3, 6 and 9 months after the day of the first assay.

The acceptance criteria for recovery was within 100 +/- 10%.

The criterion for reproducibility (CV %) was </= 10%.

Current Real Time Studies support a 8 month Shelf life at 2-8°C.

Open Vial Stability

Open vial stability of the ST AIA-PACK Progesterone III Calibrator Set was assessed by reconstituting the material according to the package insert. Samples were reconstituted and stored at refrigerated temperatures for 2 days and tested for progesterone.

The criterion for recovery was within 100 +/-10%.

The criterion for reproducibility (CV %) was </= 10%.

Current open vial studies support a reconstituted claim of 1 day when stored at 2-8°C.

9. SUMMARY OF VALUE ASSIGNMENT

The ST AIA-PACK PROG III Calibrator Set contains assigned concentrations of progesterone. The assigned value is determined on a lot-by-lot basis and is designed to provide an assay calibration range of 0.1 to 40 ng/mL of progesterone. The calibrators for use with the ST AIA-PACK PROG III were referred to through the USP (United States Pharmacopeia) Standard (Lot #I1J239).

The primary reference material was prepared by diluting the USP reference material with calibrator base and the progesterone value as reference material was assigned gravimetrically.

The values of the product calibrator were assigned using the AIA-2000 instruments with the secondary reference material as calibrator. The values were verified by comparing measured results with those obtained with the previous lot for control materials.

The value assignment was determined by analyzing 5 replicates of the test calibrator on two Tosoh AIA-2000 instruments and the mean, SD and CV calculated for each lot before release to the user. The acceptance criteria states the precision measured by the CV should be within 10%.

Progesterone (Calibrator Levels)	**N**	**Reference Value (ng/mL)**	**Mean (ng/mL)**	**CV %**
Cal (2)	5	0.5	.504	4.8
Cal (3)	5	1.5	1.53	2.2
Cal (4)	5	5.0	5.08	2.2
Cal (5)	5	15	15.0	2.0
Cal (6)	5	45	45.5	2.9

10. TRACEABILITY

ANALYTE	**SUPPLIER**	**PRODUCT NUMBER**	**ORIGIN**	**SOURCE**
Progesterone	Sigma	I1J239	Steroid stripped and lipid stripped human serum	Chemical Compound

11. CONCLUSION

Testing results indicate that the proposed device is substantially equivalent to the predicate device.