



Food and Drug Administration
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February 17, 2016

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

Re: K160113

Trade/Device Name: ST AIA-PACK hsE2 Calibrator Set
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, Secondary
Regulatory Class: Class II
Product Code: JIT
Dated: January 18, 2016
Received: January 19, 2016

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 regulation (21 CFR Part 801), 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,

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

Indications for Use

510(k) Number (if known)

K160113

Device Name

ST AIA-PACK hsE2 Calibrator Set

Indications for Use (Describe)

The ST AIA-PACK hsE2 Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK hsE2 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.

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**510(k) Summary
ST AIA-PACK hsE2 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: January 18, 2016
Submitter: Tosoh Bioscience, Inc
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Grove City, OH 43123

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**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 hsE2 Calibrator Set
Purpose of Submission: New Product
Regulatory Classification: Calibrator, Secondary
Common Name: Estradiol Test System
Classification: Class II
Product Code: JIT
Panel: Clinical Chemistry
21 CFR Number: 21 CFR 862.1260

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

Predicate Device Number: K932084
Predicate: ST AIA-PACK E2 (Calibrator Set)
Manufacturer: Tosoh Bioscience, Inc. (previously known as Tosoh Medics, Inc.)

5. INTENDED USE

The ST AIA-PACK hsE2 Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK hsE2 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 hsE2 Calibrator (1)	0 pg/mL
	Human serum containing no detectable concentration of estradiol with sodium azide as a preservative.	
2 x 1 mL	ST AIA-PACK hsE2 Calibrator (2)	25 pg/mL (approx.)
	ST AIA-PACK hsE2 Calibrator (3)	50 pg/mL (approx.)
	ST AIA-PACK hsE2 Calibrator (4)	100 pg/mL (approx.)
	ST AIA-PACK hsE2 Calibrator (5)	500 pg/mL (approx.)
	ST AIA-PACK hsE2 Calibrator (6)	1,100 pg/mL (approx.)
	Human serum containing the assigned concentration of estradiol (described on each vial) with sodium azide as a preservative.	

ST AIA-PACK hsE2 Calibrator Set

P/N # 025325

The ST AIA-PACK hsE2 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 hsE2 Calibrator Set is designed for use with ST AIA-PACK hsE2 and ST AIA-PACK hsE2 Sample Diluting Solution.

7. PREDICATE COMPARISON TABLE

Substantial Equivalence:

Comparison between the Tosoh ST AIA-PACK hsE2 Calibrator Set and the Tosoh ST AIA-PACK E2 Calibrator Set

Similarities

Characteristic	Tosoh ST AIA-PACK hsE2 Calibrator Set	Predicate Tosoh AIA-PACK E2 Calibrator Set (K932084)
Intended Use	The ST AIA-PACK hsE2 Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK hsE2 assay.	The AIA-PACK E2 Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK E2 Assays.
Indications for Use (same as Intended Use)	The ST AIA-PACK hsE2 Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK hsE2 assay.	The AIA-PACK E2 Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK E2 Assay.
Analyte	Estradiol	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
Shelf-life	12 months when stored unopened and refrigerated at 2-8°C	12 months when stored unopened and refrigerated at 2-8°C
Base	Human Serum	Human serum

Differences

Characteristic	Tosoh AIA-PACK hsE2 Calibrator Set	Predicate Tosoh AIA-PACK E2 Calibrator Set (K932084)
Traceability	IRMM (Institute for Reference Materials and Measurements) CRM577	Internal reference standards.
Levels	Six (Approximately 0, 25, 50, 100, 500 and 1100 pg/mL – lot specific)	Six (Approximately 0, 40, 100, 500, 1000 and 3250 – lot specific)

8. SUMMARY OF STABILITY STUDIES

Summary of Stability Studies

Real Time Testing

ST AIA-PACK hsE2 Calibrator Set were stored at refrigerated temperatures and assayed at 6, 12 and 13 months after the day of the first assay.

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

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

Current Real Time Studies support a 12 month Shelf life at 2-8°C.

Open Vial Stability

Open vial stability of the ST AIA-PACK hsE2 Calibrator Set was assessed by reconstituting the material according to the package insert. Samples were reconstituted and stored at refrigerated temperatures for 0, 7 and 8 days and tested for estradiol.

The criterion for recovery was 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 hsE2 Calibrator Set contains assigned concentrations of estradiol. The assigned value is determined on a lot-by-lot basis and is designed to provide an assay calibration range of 7 to 1,000 pg/mL of estradiol. The calibrators in this set are referenced to the IRMM (Institute for Reference Materials and Measurements) CRM577.

The Tosoh AIA-PACK hsE2 Calibrator, 1st Standard Series of (2) to (6) was prepared by diluting the 17β -estradiol (purchased from SIGMA) with the calibrator base matrix free of estradiol. Calibrators (2) through (6) were value assigned according to the dilution ratio. The base matrix was used as the zero (0) calibrator.

The value of the Tosoh AIA-PACK hs E2 Calibrator 2nd Standard was assigned using the primary reference material as calibrator. The mean value of 5 replicates on each of 2 analyzers and 3 lots of reagent was calculated. The grand mean, SD and CV (%) was calculated from the mean values. The acceptance criteria of the grand mean is <10% CV. The grand mean value is the assigned value if this criteria is met.

The value assignment for the Tosoh ST-AIA PACK hsE2 Calibrator was determined by analyzing 5 replicates of the calibrator on 2 analyzers and 3 lots of reagent using the 2nd Standard as the calibrator. The mean value from the 5 replicates on each analyzer and each lot was calculated as above. The grand mean, SD and CV (%) was calculated from the mean values. The acceptance criteria of the grand mean is <10% CV. The grand mean value is the assigned value if this criteria is met.

hsE2 (Calibrator Levels)	N	Reference Value (pg/mL)	Grand Mean (pg/mL)	CV %
Cal (2)	5	25	26.8	6.3
Cal (3)	5	50	52.6	2.5
Cal (4)	5	100	102	1.9
Cal (5)	5	500	519	2.1
Cal (6)	5	1100	1120	1.5

10. TRACEABILITY

ANALYTE	SUPPLIER	PRODUCT NUMBER	ORIGIN	SOURCE
Estradiol	Sigma	E8875	Derived from a plant source	Chemical Compound

11. CONCLUSION

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