Tosoh Bioscience, Inc.

K063605

JUN 21 2007

510(k) SUMMARY

Submitted By: Charles P. Gill
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This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.2.

Name of Device:
Trade Name: ST AIA-PACK Intact PTH Assay

Classification Name: Parathyroid Hormone Test System

Predicate Device: Roche Diagnostics Corp., Elecsys Parahyroid Hormone Test System K992680

Intended Use: The Tosoh Bioscience, Inc. ST AIA-PACK Intact PTH is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Intact Parathyroid Hormone (Intact PTH) in human serum and EDTA plasma on specific TOSOH AIA System analyzers.

The Tosoh AIA-PACK Intact PTH CONTROL SET is intended for IN VITRO DIAGNOSTIC USE ONLY for performing quality control procedures with the ST AIA-PACK Intact PTH Assay

The Tosoh AIA-PACK Intact PTH CALIBRATOR SET is intended for IN VITRO DIAGNOSTIC USE ONLY for the calibration of the ST AIA-PACK Intact PTH.

Device Description: The ST AIA-PACK Intact PTH is a two-site immunoenzymometric assay which is performed entirely in the AIA-PACK Intact PTH present in the test sample is bound with polyclonal antibody immobilized on magnetic beads and enzyme-labeled polyclonal antibody in the AIA- PACK.

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Performance Characteristics:

Parameter	**Performance Results**
Limit of Detection	≈1.0 pg/ml
Assay Range	1 – 2200 pg/ml
Total Precision	Sample / Mean (pg/ml) / STDV (pg/ml) / CV% Serum A3 / 27.7 / 1.005 / 3.6 Serum B3 / 243.6 / 8.936 / 3.7 Serum C3 / 1123.5 / 44.540 / 4.0 Plasma A3 / 27.1 / 1.320 / 4.9 Plasma B3 / 247.1 / 11.497 / 4.7 Plasma C3 / 1217.2 / 44.159 / 3.6
Correlation	Number of samples Measured: 153 Y = 1.013x – 10.457 R = 0.997
Recovery (Mean ±SD%)	Sample / Percent Recovery (%) Serum A1 / 100.3, 103.0, 100.6 Serum B1 / 109.0, 103.6, 98.1 Serum C1 / 108.5, 107.8, 99.8 Plasma A1 / 108.8, 106.0, 104.4 Plasma B1 / 108.4, 104.3, 106.4 Plasma C1 / 104.2, 105.7, 100.4
Endogenous Substance Interferences	Interference is defined to be recovery outside of 10% of the known specimen mean concentration. • Hemoglobin (up to 440 mg/dL), free bilirubin (up to 17 mg/dL) and conjugated bilirubin (up to 17 mg/dL) do not interfere with the assay.
Sample types	Serum and/or EDTA Plasma
Reference Ranges	The interval given here was determined in EDTA plasma samples. Reference interval = 8.2 – 83.5 pg/mL Sample Range = 9.5 – 98 pg/ml

Conclusions: This data demonstrates the safety and effectiveness of the ST AIA-PACK Intact PTH Assay for its intended in vitro diagnostic use.

The magnetic beads are washed to remove unbound enzyme-labeled polyclonal antibody and are then incubated with a fluorogenic substrate 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled polyclonal antibody that binds to the beads is directly proportional to Intact PTH concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

Technological Comparison to Predicate:

Assay / Feature	ST AIA-PACK Intact PTH	Roche Elecsys Intact PTH assay (k992680)
Analyte	Human Parathyroid Hormone	Human Parathyroid Hormone
Intended Use	The Tosho Bioscience, Inc. ST AIA-PACK Intact PTH is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Intact Parathyroid Hormone (Intact PTH) in human serum and EDTA plasma on specific TOSOH AIA System analyzers.	For the quantitative determination of intact parathyroid hormone and for differential diagnosis of hypercalcemia and hypocalcemia.
Specimen	EDTA – Plasma	EDTA – Plasma
Assay Format	IEMA	ICMA
Result Read Time	Approximately 20 Minutes	9 – 18 minutes
Analytical Sensitivity	≈1.0 pg/ml	≈ 1.20 pg/ml
Normal Range	8.2 – 83.5 pg/ml	15 – 65 pg/ml

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tosoh Bioscience, Inc.
c/o Charles Gill
3600 Gantz Road
Grove City, OH 43123

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Re: k063605
Trade/Device Name: ST AIA-PACK Intact PTH; ST AIA-PACK Intact PTH CALIBRATOR SET; ST AIA-PACK Intact PTH CONTROL SET
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW, JIT, JJX
Dated: June 13, 2007
Received: June 20, 2007

Dear Mr. Gill:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063605

Device Name: ST AIA-PACK Intact PTH

Indications For Use: ST AIA-PACK Intact PTH is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of the levels of parathyroid hormone in human serum and EDTA plasma on specific TOSOH AIA System analyzers. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K063605

Indications for Use

510(k) Number (if known):	K063605
Device Name:	ST AIA-PACK Intact PTH CALIBRATOR SET
Indications For Use:	The ST AIA-PACK Intact PTH CALIBRTOR SET is intended for IN VITRO DIAGNOSTIC USE ONLY for the calibration of the ST AIA-PACK Intact PTH.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

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Office of In Vitro Diagnostic Device
Evaluation and Safety

K063605

Indications for Use

510(k) Number (if known):	K063605
Device Name:	AIA-PACK Intact PTH CONTROL SET
Indications For Use:	The AIA-PACK Intact PTH CONTROL SET is intended for IN VITRO DIAGNOSTIC USE ONLY for performing quality control procedures with the ST AIA-PACK Intact PTH Assay.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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