k123379

NOV 2 7 2012

Attachment B
510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Name:

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Regulatory Affairs
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Device Name:

Classification Name: Radioimmunoassay, Free Thyroxine

Trade Name: Abbott ARCHITECT Free T_4

Common Name: Radioimmunoassay, Free Thyroxine

Governing Regulation: 862.1695

Device Classification: Class II

Classification Panel: Clinical Chemistry

Product Code: CEC/JIT/JJX

Legally marketed device to which equivalency is claimed:

k983417, Abbott ARCHITECT Free T4 (LN 7K65-01; 2-point calibration)

Attachment B (Continued)
510(k) Summary (Summary of Safety and Effectiveness)

Intended Use of Device:

The ARCHITECT Free T4 (FT4) assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of free thyroxine (Free T4) in human serum and plasma. The ARCHITECT Free T4 assay is to be used as an aid in the assessment of thyroid status.

The ARCHITECT Free T4 Calibrators are for the calibration of the ARCHITECT i System when used for the quantitative determination of free thyroxine (Free T4) in human serum and plasma when using the ARCHITECT Free T4 Reagent Kit.

The ARCHITECT Free T4 Controls are for the verification of the accuracy and precision of the ARCHITECT i System when used for the quantitative determination of free thyroxine (Free T4) in human serum and plasma when using the ARCHITECT Free T4 Reagent Kit.

Description of Device:

The ARCHITECT Free T_4 assay is a two-step immunoassay to determine the presence of free thyroxine (Free T_4) in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and anti-T_4 coated paramagnetic microparticles are combined. Free T_4 (unbound) present in the sample binds to the anti-T_4 coated microparticles. After washing, T_3 acridinium labeled conjugate is added in the second step. Pre-Trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). An inverse relationship exists between the amount of Free T_4 in the sample and the RLUs detected by the ARCHITECT *i* optical system.

The calibrators are devices intended for medical purposes for use in the ARCHITECT Free T_4 assay test system to establish points of reference that are used in the quantitative determination of values in the measurement of substances in human specimens. Free T_4 measurements are used as an aid in the assessment of thyroid status.

Modification of Device:

This Special 510(k) modification of the ARCHITECT Free T_4 assay consisted of changing the calibration from a 2-point calibration to a 6-point calibration.

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510(k) Summary (Summary of Safety and Effectiveness)

Similarities and Differences of Modified Device:

The table below compares the new device, ARCHITECT Free T_4 (LN 7K65-02; 6-point calibration), with the predicate device, ARCHITECT Free T_4 (LN 7K65-01; 2-point calibration) (k983417).

Attribute	Predicate Device ARCHITECT Free T_4 (2-point calibration) LN 7K65-01, k983417	New Device ARCHITECT Free T_4 (6-point calibration) LN 7K65-02
Intended Use	The ARCHITECT Free T4 (FT4) assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of free thyroxine (Free T4) in human serum and plasma. The ARCHITECT Free T4 assay is to be used as an aid in the assessment of thyroid status. The ARCHITECT Free T4 Calibrators are for the calibration of the ARCHITECT i System when used for the quantitative determination of free thyroxine (Free T4) in human serum and plasma when using the ARCHITECT Free T4 Reagent Kit. The ARCHITECT Free T4 Controls are for the verification of the accuracy and precision of the ARCHITECT i System when used for the quantitative determination of free thyroxine (Free T4) in human serum and plasma when using the ARCHITECT Free T4 Reagent Kit.	Same
Instrumentation	ARCHITECT *i* System	Same

Attachment B (Continued)
510(k) Summary (Summary of Safety and Effectiveness)

Similarities and Differences of Modified Device (Continued):

Attribute	Predicate Device ARCHITECT Free T_4 (2-point calibration) LN 7K65-01, k983417	New Device ARCHITECT Free T_4 (6-point calibration) LN 7K65-02
Assay Reagents	Microparticles: Anti-T_4 (sheep) coated microparticles in TRIS buffer with sheep IgG stabilizers. Minimum concentration: 0.08% solids. Preservative: antimicrobial agent. Conjugate: T3 acridinium-labeled conjugate in MES buffer with NaCl and Triton X-100 stabilizers. Minimum concentration: 0.2 ng/mL. Preservative: ProClin.	• Same
Free T_4 Calibrators	• 2 levels • 0.5 and 6.0 ng/dL L-thyroxine in human serum	• 6 levels • 0.0, 0.5, 1.0, 2.0, 3.5, 6.0 ng/dL L-thyroxine in human serum
Calibrator Composition	• Calibrators 1-2: L-thyroxine, sodium salt pentahydrate (HPLC grade) • Calibrators 1-2: Diluent: Human Serum • Calibrators 1-2: Preservative: Sodium Azide	• Calibrators B-F: Same • Calibrators A-F: Diluent: Same • Calibrators A-F: Preservative: Same
Standardization	The calibrators are matched to an Abbott internal reference standard. This internal reference standard is manufactured by gravimetric methods based on the Free Thyroxine calculation (FT_4c) using L-Thyroxine, sodium salt pentahydrate (HPLC grade), at each concentration, which depends on the amount of Total T_4 found in the serum and the serum's T_4 binding capacity.	Same
Calibrator Range	0.0–6.0 ng/dL	Same

Attachment B (Continued)
510(k) Summary (Summary of Safety and Effectiveness)

Similarities and Differences of Modified Device (Continued):

Attribute	Predicate Device ARCHITECT Free T_4 (2-point calibration) LN 7K65-01, k983417	New Device ARCHITECT Free T_4 (6-point calibration) LN 7K65-02
Analytical Sensitivity	0.4 ng/dL	Analytical sensitivity replaced by LoQ.
LoB LoD LoQ	Not applicable	LoB: 0.22 ng/dL LoD: 0.28 ng/dL LoQ: 0.4 ng/dL
Dynamic Range/ Measuring Interval	0.4–6.0 ng/dL	Same
Control Composition	• Controls L, M, H: L-thyroxine, sodium salt pentahydrate (HPLC grade) • Controls L, M, H: Diluent: Human Serum • Controls L, M, H: Preservative: Sodium Azide	• Controls L, M, H: Same • Controls L, M, H: Diluent: Same • Controls L, M, H: Preservative: Same

Attachment B (Continued)
510(k) Summary (Summary of Safety and Effectiveness)

Verification/Validation of Modification:

The nonclinical performance of the ARCHITECT Free T_4 assay was demonstrated through the following studies:

- Accuracy by Correlation
- Accelerated Calibrator Stability
- Real Time Calibrator Stability – In-Use (Open Vial)
- Real Time Calibrator Stability – Intended Storage (Closed Vial)
- Limits of Blank/Detection/Quantitation (LoB/LoD/LoQ)
- Linearity
- 20-Day Precision at the Limits of the Measuring Interval
- 20-Day Precision to Verify the Product Requirements
- 20-Day Precision for Native Samples

Conclusion:

Substantial equivalence for the modified device, ARCHITECT Free T_4 (LN 7K65-02; 6-point calibration), is claimed to the predicate device cleared in k983417, ARCHITECT Free T_4 (LN 7K65-01; 2-point calibration). The modification to the calibrators, which consisted of changing the calibration from a 2-point calibration to a 6-point calibration, has not changed the intended use, as described in the labeling, nor has it altered the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 27, 2012

Abbott Laboratories
c/o Jacek Gorzowski
100 Abbott Park Road
Dept. 9VA, AP5N-2
Abbott Park, IL 60064-3500

Re: k123379
Trade/Device Name: Abbott ARCHITECT Free T4
Regulation Number: 21 CFR 862.1695
Regulation Name: Free thyroxine test system
Regulatory Class: Class II
Product Code: CEC, JIT, JJX
Dated: October 30, 2012
Received: November 1, 2012

Dear Jacek Gorzowski:

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 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 Part 801); 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123379

Device Name: Abbott ARCHITECT Free T_4

Indications for Use

The ARCHITECT Free T_4 (FT4) assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of free thyroxine (Free T_4) in human serum and plasma. The ARCHITECT Free T_4 assay is to be used as an aid in the assessment of thyroid status.

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The ARCHITECT Free T_4 Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of free thyroxine (Free T_4) in human serum and plasma when using the ARCHITECT Free T_4 Reagent Kit.

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 Diagnostics and Radiological Health (OIR)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) k123379