



Food and Drug Administration
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ABBOTT LABORATORIES
LISA LUKOWSKI
REGULATORY AFFAIRS PROJECT MANAGER
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ABBOTT PARK IL 60064

July 10, 2015

Re: K151566

Trade/Device Name: ARCHITECT Total T4 Calibrators

Regulation Number: 21 CFR 862.1150

Regulation Name: Calibrator

Regulatory Class: II

Product Code: JIT

Dated: June 9, 2015

Received: June 10, 2015

Dear Lisa Lukowski:

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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
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Division of Chemistry and Toxicology Devices
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Enclosure

Indications for Use

510(k) Number (if known)

k151566

Device Name

ARCHITECT Total T4 Calibrators

Indications for Use (Describe)

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

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

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.

I. Applicant Name

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Date Summary prepared: July 9, 2015

II. Device Name

Trade Name: ARCHITECT Total T₄ Calibrators
Device Classification: Class II
Classification Name: Calibrator, Secondary
Governing Regulation: 862.1150
Code: JIT

Classification Panel: Clinical Chemistry

510(k) Number: k151566

III. Predicate Device

ARCHITECT Total T₄ Calibrators (k983440)

IV. Description of the Device

The calibrators are devices intended for medical purposes for use in the ARCHITECT Total T₄ 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. Total T₄ measurements are used as an aid in the assessment of thyroid status.

The calibrators are designed to be used on the ARCHITECT *i* System (*i* 2000_{SR}, *i* 2000, and *i* 1000_{SR}) with the ARCHITECT Total T₄ Reagents.

ARCHITECT Total T₄ Calibrator kit contains:

Component	Number of Bottles × Volume
Calibrator A (Cal A)	1 × 4 mL
Calibrator B (Cal B)	1 × 4 mL
Calibrator C (Cal C)	1 × 4 mL
Calibrator D (Cal D)	1 × 4 mL
Calibrator E (Cal E)	1 × 4 mL
Calibrator F (Cal F)	1 × 4 mL

- ARCHITECT Total T₄ Calibrator A contains human serum. Preservative: Sodium Azide.
- ARCHITECT Total T₄ Calibrators B–F contain different concentrations of T₄ prepared in human serum. Preservative: Sodium Azide.

The ARCHITECT Total T₄ Calibrators are prepared to target the following concentrations:

Component	Concentration (µg/dL)	Concentration (nmol/L)
Calibrator A (Cal A)	0.0	0.0
Calibrator B (Cal B)	3.0	38.6
Calibrator C (Cal C)	6.0	77.2
Calibrator D (Cal D)	12.0	154.4
Calibrator E (Cal E)	18.0	231.7
Calibrator F (Cal F)	24.0	308.9

Value Assignment:

The ARCHITECT Total T₄ (TT₄) calibrators are prepared using a stock solution and then value assigned using primary calibrators (Abbott internal reference standards prepared using USP material). The TT₄ calibrator values must meet the sponsor's predetermined acceptance criteria within a set specification, determined by the manufacturer. Each new TT₄ calibrator lot is value assigned prior to use. Before each lot is released, the TT₄ calibrators are run on 3 instruments, 1 run per instrument 15 replicates per run. The observed values must meet the manufacture's acceptance criteria.

V. Intended Use of the Device

The ARCHITECT Total T₄ Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of thyroxine (Total T₄) in human serum and plasma.

VI. Summary of Technological Characteristics

The following table provides the similarities and differences between the candidate (ARCHITECT Total T₄) and the predicate device (ARCHITECT Total T₄, k983440).

Comparison of ARCHITECT Total T₄ to Predicate ARCHITECT Total T₄ Calibrators

Attribute	Predicate Device ARCHITECT Total T₄ Calibrators (2-Point Calibration) k983440	Candidate Device ARCHITECT Total T₄ Calibrators (6-Point Calibration) k151566
Intended Use	The ARCHITECT Total T ₄ Calibrators are for the calibration of the ARCHITECT <i>i</i> System when used for the quantitative determination of thyroxine (Total T ₄) in human serum and plasma.	Same
Instrumentation	ARCHITECT <i>i</i> System (<i>i</i> 2000 _{SR} , <i>i</i> 2000, and <i>i</i> 1000 _{SR})	Same

**Comparison of ARCHITECT Total T₄ to
Predicate ARCHITECT Total T₄ Calibrators**

Attribute	Predicate Device ARCHITECT Total T₄ Calibrators (2-Point Calibration) k983440	Candidate Device ARCHITECT Total T₄ Calibrators (6-Point Calibration) k151566
Total T ₄ Calibrators	<ul style="list-style-type: none"> • 2 levels • 0.0 and 18.0 µg/dL L-Thyroxine in human serum 	<ul style="list-style-type: none"> • 6 levels • 0.0, 3.0, 6.0, 12.0, 18.0, and 24.0 µg/dL L-Thyroxine in human serum
Calibrator Composition	<ul style="list-style-type: none"> • Calibrator 1: Analyte: None Diluent: Human Serum Preservative: Sodium Azide • Calibrator 2: Analyte: L-Thyroxine Diluent: Human Serum Preservative: Sodium Azide 	<ul style="list-style-type: none"> • Calibrator A: Analyte: None Diluent: Human Serum Preservative: Sodium Azide • Calibrators B–F: Analyte: L-Thyroxine Diluent: Human Serum Preservative: Sodium Azide
Standardization	The calibrators are matched to an Abbott internal reference standard. This internal reference standard is manufactured by gravimetric methods using USP reference L-Thyroxine.	Same
Storage and Stability	The calibrators are stable until the expiration date when stored and handled as directed at 2-8°C.	The expiration date is 12 months from the date opened when stored and handled as directed. Do not exceed the lot expiration date printed on the bottle. The calibrators are stable until the expiration date when stored and handled as directed.
Preparation for Use	Ready to use	Same

Stability Results:

Stability studies for the ARCHITECT Total T₄ calibrators were performed based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP25-A.

In-Use Condition (Open Vial):

Stability of the ARCHITECT Total T₄ Calibrators was evaluated. At the baseline time point (0) and each subsequent time point (1, 2, 3, 4, 6, 9 and 12 months) the on-test calibrator vials are opened and squeezed to ensure good air exchange, then inverted and squeezed to release a minimum of 8 drops of material from each vial. The vials are then closed and stored at 2 to 8°C until the next time point. In-use testing was performed using a minimum of 10 replicates each of the on-test calibrators, reference controls, and reference panel with the designated reference reagents. The time point results were evaluated against the stability limit evaluation criteria. The results support the following stability claim for the ARCHITECT Total T₄ Calibrators: 12 months at 2 – 8°C.

Intended Storage Condition (Closed Vial):

The stability for the ARCHITECT Total T₄ Calibrators was evaluated using real-time stability study. For the real time stability study, three lots of test materials are stored at 2 – 8°C. Samples at time-points 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 months were tested and evaluated against the stability limit evaluation criteria. The results support the following stability claim for the ARCHITECT Total T₄ Calibrators: 14 months at 2 – 8°C.

Standardization

The calibrators are matched to an Abbott internal reference standard. This internal reference standard is manufactured by gravimetric methods using USP reference L-Thyroxine.

VII. Conclusion

Substantial equivalence for the candidate device, ARCHITECT Total T₄ Calibrators, is claimed to the predicate device cleared in k983440, ARCHITECT Total T₄ Calibrators. The modifications to the calibrators have not changed the intended use, as described in its labeling, nor have the modifications altered the fundamental scientific technology of this device.