DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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ABBOTT LABORATORIES
LINDA SOHN
SR. REGULATORY SPECIALIST
100 ABBOTT PARK ROAD, DEPT 09AA, BLDG. AP08
ABBOTT PARK, IL 60064

February 15, 2017

Re: K170160
Trade/Device Name: ARCHITECT Free T3 Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: January 17, 2017
Received: January 18, 2017

Dear Linda Sohn:

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)*
k170160

Device Name
ARCHITECT Free T3 Calibrators

Indications for Use *(Describe)*
The ARCHITECT Free T3 Calibrators are for the calibration of the ARCHITECT i System when used for the quantitative determination of free triiodothyronine (Free T3) 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.

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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.

I. Applicant Name

Abbott Laboratories
Dept. 9AA, AP8-1
100 Abbott Park Road
Abbott Park, IL 60064

Primary contact person for all communications:

Linda Sohn, ADD, Sr. Regulatory Affairs Specialist
Phone: (224) 667-4846
Fax: (224) 667-4836
E-Mail: linda.sohn@abbott.com

Secondary contact person for all communications:

Mary Caren Murawski, Associate Director of Regulatory Affairs
Phone: (224) 667-2817
Fax: (224) 667-4836
E-Mail: mary.murawski@abbott.com

Date Summary prepared: February 13, 2017

II. Device Name

Trade Name: ARCHITECT Free T_3 Calibrators
Device Classification: Class II
Classification Name: Calibrator, Secondary
Governing Regulation: 862.1150
Code: JIT

Classification Panel: Clinical Chemistry

510(k) Number: k170160

III. Predicate Device

ARCHITECT Free T_3 Calibrators (K983439)

IV. Description of the Device

The calibrators are devices intended for medical purposes for use in the ARCHITECT Free T_3 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_3 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 Free T_3 Reagents.

The ARCHITECT Free T_3 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 Free T_3 Calibrator A contains human serum. Preservative: Sodium Azide

- ARCHITECT Free T_3 Calibrators B through F contain different concentrations of L-Thyroxine and L-Triiodothyronine prepared in human serum. Preservative: Sodium Azide.

The ARCHITECT Free T_3 Calibrators are prepared to target the following concentrations:

Component	Concentration (pg/mL)	Concentration (pmol/L)
Calibrator A (Cal A)	0.0	0.0
Calibrator B (Cal B)	1.4	2.15
Calibrator C (Cal C)	3.5	5.38
Calibrator D (Cal D)	7.0	10.75
Calibrator E (Cal E)	17.2	26.42
Calibrator F (Cal F)	30.0	46.08

Value Assignment

The ARCHITECT Free T_3 standardization follows a two-step assay standardization method, where market Free T_3 Calibrator lots are matched to Primary Calibrators using sample/reference (S/C ratio) specifications. The Primary Calibrators are matched to Working Reference Calibrators (Abbott internal reference standards) using sample/reference (S/C ratio) specifications. The Working Reference Calibrators are manufactured by gravimetric methods using L-Triiodothyronine (Liothyronine USP) and L-Thyroxine (Levothyroxine USP).

V. Intended Use of the Device

The ARCHITECT Free T_3 Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of free triiodothyronine (Free T_3) in human serum and plasma.

VI. Summary of Technological Characteristics

The following table provides the similarities and differences between the candidate calibrators ARCHITECT Free T_3 and the predicate calibrators (ARCHITECT Free T_3, K983439).

Comparison of ARCHITECT Free T_3 to Predicate ARCHITECT Free T_3 Assay

Attribute	Predicate Device ARCHITECT Free T_3 Calibrators (2-Point Calibration), K983440	Candidate Device ARCHITECT Free T_3 Calibrators (6-Point Calibration)
Intended Use	The ARCHITECT Free T_3 Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of free triiodothyronine (Free T_3) in human serum and plasma.	Same
Instrumentation	ARCHITECT *i* System (*i* 2000_{SR}, *i* 2000, and *i* 1000_{SR})	Same
Free T_3 Calibrators	• 2 levels • 1.4 and 30 pg/mL L-Thyroxine and L-Triiodothyronine in human serum	• 6 levels • 0.0, 1.4, 3.5, 7.0, 17.2, 30.0 pg/mL L-Thyroxine and L-Triiodothyronine in human serum
Calibrator Composition	• Calibrator 1: Analyte: None Diluent: Human Serum Preservative: Sodium Azide • Calibrator 2: Analyte: L-Thyroxine and L-Triiodothyronine Diluent: Human Serum Preservative: Sodium Azide	• Calibrator A: Analyte: None Diluent: Human Serum Preservative: Sodium Azide • Calibrators B–F: Analyte: L-Thyroxine and L-Triiodothyronine Diluent: Human Serum Preservative: Sodium Azide

Attribute	Predicate Device ARCHITECT Free T_3 Calibrators (2-Point Calibration), K983440	Candidate Device ARCHITECT Free T_3 Calibrators (6-Point Calibration)
Standardization	The calibrators are matched to an Abbott internal reference standard. This internal reference standard is manufactured by gravimetric methods based on the Free Triiodothyronine calculation (FT3c) using L-Triiodothyronine (sodium salt, not less than 95% pure by HPLC) and L-Thyroxine (sodium pentahydrate, not less than 95% pure by HPLC) at each concentration level. The FT3c is a calculation of the Free Triiodothyronine hormone concentration, which depends on the amount of Total T_3 and Total T_4 found in the serum as well as the serum's thyroid hormone binding capacity.	Same
Storage and Stability	The calibrators are stable until the expiration date when stored and handled as directed at 2-8°C	Same
Preparation of Use	Ready to use	Same

Stability Results

Stability studies for the ARCHITECT Free T_3 Calibrators were performed based on guidance from the Clinical Laboratories and Standards Institute (CLSI) document EP25-A.

In-Use Condition (Open Vial)

The stability of the ARCHITECT Free T_3 Calibrators was evaluated. At the baseline time point (0) and each subsequent time point (1, 2, 3, 4, 6, 8, and 11 months), the on-test calibrator vials were 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 were 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 a stability claim for the ARCHITECT Free T_3 Calibrators of 11 months at 2 to 8°C. The in-use stability is an on-going study and is scheduled to continue for up to 18 months.

Intended Storage Condition (Closed Vial)

The stability of the ARCHITECT Free T_3 Calibrators was evaluated using a real-time stability study. For the real time stability study, three lots of test material were stored at 2 to 8°C. Samples at time points 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 months were tested and evaluated against the stability limit evaluation criteria. The results for the Intended Use stability support a stability claim of 12 months at 2 to 8°C.

The results for In-Use and Intended Storage stability studies support a stability claim for the ARCHITECT Free T_3 Calibrators of 11 months at 2 to 8°C. The in-use and intended storage stability is an on-going study and is scheduled to continue for up to 18 months.

Standardization

The calibrators are matched to an Abbott internal reference standard. This internal reference standard is manufactured by gravimetric methods based on the Free Triiodothyronine calculation (FT3c) using L-Triiodothyronine (sodium salt, not less than 95% pure by HPLC) and L-Thyroxine (sodium pentahydrate, not less than 95% pure by HPLC) at each concentration level. The FT3c is a calculation of the Free Triiodothyronine hormone concentration, which depends on the amount of Total T_3 and Total T_4 found in the serum as well as the serum‘s thyroid hormone binding capacity.

VII. Conclusion

Substantial equivalence for the candidate device, ARCHITECT Free T_3 Calibrators, is claimed to the predicate device cleared in K983439, ARCHITECT Free T_3 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.