DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 27, 2017

ABBOTT LABORATORIES
LINDA SOHN
REGULATORY AFFAIRS PROJECT MANAGER
DEPT. 09AA, BLDG. AP08
100 ABBOTT PARK ROAD
ABBOTT PARK IL 60064

Re: K173122
Trade/Device Name: ARCHITECT Free T4
Regulation Number: 21 CFR 862.1695
Regulation Name: Free thyroxine test system
Regulatory Class: II
Product Code: CEC
Dated: September 28, 2017
Received: September 29, 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,

Kellie B. Kelm -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k173122

Device Name
ARCHITECT Free T4

Indications for Use *(Describe)*

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.
ARCHITECT Free T4 (FT4) assay is to be used as an aid in the assessment of thyroid status.

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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I. 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.

Date: September 28, 2017

Applicant Name:

Linda Sohn, ADD, Regulatory Affairs Project Manager
Abbott Laboratories Diagnostics Division
Dept. 09AA, AP08
100 Abbott Park Road
Abbott Park, IL 60064
Telephone Number: (224) 667-4846
Fax Number: (224) 667-4836

Device Name:

Reagents

Classification Name: Free thyroxine test system
Trade Name: Abbott ARCHITECT Free T_4
Common Name: Radioimmunoassay, Free Thyroxine
Governing Regulation: 21 CFR 862.1695
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: CEC

Legally marketed device to which equivalency is claimed:

ARCHITECT Free T_4 (cleared under k123379 on November 27, 2012)

Intended Use/Indications for Use:

The ARCHITECT Free T_4 (FT_4) assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of free thyroxine (Free T_4) in human serum and plasma.

ARCHITECT Free T_4 (FT_4) assay is to be used as an aid in the assessment of thyroid status.

Description of Device

The ARCHITECT Free T_4 assay is a two-step immunoassay for the quantitative determination 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 to create a reaction mixture. Following another wash cycle, pre-trigger and trigger solutions are 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* System optics.

Modification of Device:

This Special 510(k) modification of the ARCHITECT Free T_4 assay consisted of proposed labeling change for reduced microparticle percent solids from 0.08% to 0.05% due to enhancement of our manufacturing process, and proposed labeling change for reduced measuring interval from 0.40 to 6.00 ng/dL to 0.40 to 5.00 ng/dL.

Similarities and Differences of Modified Device

The table below compares the modified device, (ARCHITECT Free T_4) and the predicate device (ARCHITECT Free T_4 [k123379]).

Characteristics	Predicate Device (k123379)	Modified Device
Intended Use /	The ARCHITECT Free T_4 (FT_4) assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of Free T_4 in human serum and plasma.	
Indications for Use	ARCHITECT Free T_4 (FT_4) assay is to be used as an aid in the assessment of thyroid status.	
Platform	ARCHITECT *i* System	
Methodology	Chemiluminescence (CMIA)	
Specimen Type	Serum and plasma	
Microparticles	Anti-T4 (sheep) coated Microparticles in TRIS buffer with sheep IgG stabilizers. Preservative: sodium azide. Percent solids: 0.08%	Same Percent solids: 0.05%
Conjugate	T3 acridinium-labeled Conjugate in MES buffer with NaCl and Triton X-100 stabilizers. Preservative: ProClin. Minimum concentration: 0.2 ng/mL.	same
Calibrators	• 6 levels • 0.0, 0.5, 1.0, 2.0, 3.5, 6.0 ng/dL L-thyroxine in human serum	same
Measuring Interval	0.40–6.00 ng/dL	0.40–5.00 ng/dL

Verification of Modification:

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

- Limit of Blank/Detection/Quantitation
- Precision (20-Day)
- Precision at Limits of Measuring Interval
- Accuracy by Correlation
- Accelerated Life Testing (ALT) Stability
- Reagent On Board Stability
- Linearity

The device passed all of the tests based on pre-determined acceptance criteria.

Conclusion:

Substantial equivalence for the modified device, ARCHITECT Free T_4 is claimed to the predicate device cleared in k123379, ARCHITECT Free T_4. The modifications to the labeling, which consisted of proposed labeling change for reduced microparticle percent solids from 0.08% to 0.05%, and proposed labeling change for reduced measuring interval from 0.40 to 6.00 ng/dL to 0.40 to 5.00 ng/dL, has not changed the intended use, indications for use, nor has it altered the fundamental scientific technology of the device. Furthermore, no new risks or modes of control that affect the safety and effectiveness of the device were identified as a result of the proposed change.