



ABBOTT LABORATORIES  
REGINA KUMAR  
DIAGNOSTICS DIVISION  
100 ABBOTT PARK RD  
ABBOTT PARK IL 60064

December 17, 2015

Re: K152155

Trade/Device Name: ARCHITECT 2nd Generation Testosterone  
Regulation Number: 21 CFR 862.1680  
Regulation Name: Testosterone test system  
Regulatory Class: I, Reserved  
Product Code: CDZ  
Dated: November 13, 2015  
Received: November 16, 2015

Dear Regina Kumar:

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

## Indications for Use

510(k) Number (if known)

k152155

Device Name

ARCHITECT 2nd Generation Testosterone

Indications for Use (Describe)

The ARCHITECT 2nd Generation Testosterone assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of testosterone in human serum and plasma.

Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## **I. 510(k) Summary**

The 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:** December 14, 2015

### **Applicant Name:**

Regina Xavier Kumar, Regulatory Affairs Project Manager  
Abbott Laboratories Diagnostics Division  
100 Abbott Park Road  
Abbott Park, IL 60064  
Phone: 224-668-8093  
Fax: 224-667-4836

### **Device Name:**

#### **Reagents**

Classification Name: Radioimmunoassay, Testosterones and Dihydrotestosterones  
Trade Name: ARCHITECT 2nd Generation Testosterone  
Governing Regulation: 21 CFR 862.1680  
Device Classification: Class I, Reserved  
Classification Panel: Clinical Chemistry  
Product Code: CDZ

### **Legally marketed device to which equivalency is claimed:**

ARCHITECT 2nd Generation Testosterone (cleared under K120009 on September 11, 2012)

### **Intended Use/Indications for Use:**

The ARCHITECT 2nd Generation Testosterone assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of testosterone in human serum and plasma.

Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

**Description of Device:**

The ARCHITECT 2nd Generation Testosterone assay is a delayed one-step immunoassay for the quantitative determination of testosterone in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample, assay specific diluent, and anti-testosterone (sheep, monoclonal) coated paramagnetic microparticles are combined. Testosterone present in the sample binds to the anti-testosterone coated microparticles. After incubation, testosterone acridinium-labeled conjugate is added to the reaction mixture. After further incubation and washing, 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 testosterone in the sample and the RLUs detected by the ARCHITECT *i* System optics. The concentration of testosterone is interpolated from a calibration curve established with calibrators of known testosterone concentration.

**Comparison of Technological Characteristics:**

Both the submission device (ARCHITECT 2nd Generation Testosterone) and the predicate device (ARCHITECT 2nd Generation Testosterone [K120009]) have the same technological characteristics. Both devices use a chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative determination of testosterone in human serum and plasma. There are no technological differences between the submission and predicate devices.

**Comparison of Assay Performance:**

The reagents, calibrators, and controls for the submission device and the predicate device are the same. The submission is to update the expected values section of the labeling to include the Free Testosterone Index (FTI) (also known as Free Androgen Index [FAI]). The risk analysis was performed and there is no change in the performance of the previously cleared assay. The performance data provided in K120009 still apply.

### **Summary of Supporting Data:**

The ARCHITECT 2nd Generation Testosterone expected values study was conducted in 2012 and is currently provided in the existing ARCHITECT 2nd Generation Testosterone reagent insert. A second study was conducted in 2014 to calculate FTI or FAI using ARCHITECT 2nd Generation Testosterone (List Number [LN] 2P13) and ARCHITECT SHBG (LN 8K26) assay results. The %FTI or %FAI calculated as  $\frac{[\text{Total Testosterone}]}{[\text{SHBG}]}$  provides an index of free testosterone status. The % FTI or % FAI correlates with the value of free testosterone.

### **ARCHITECT 2nd Generation Testosterone FTI/FAI Performance Study**

Testing was performed on a minimum of 120 samples from individuals in the following categories: normal males 21-49 years of age, normal males  $\geq 50$  years of age, premenopausal normal females 21-49 years of age, and postmenopausal normal females  $\geq 50$  years of age not on hormone replacement therapy.

The following inclusion/exclusion criteria apply to the study:

Samples that were within the expected values of the ARCHITECT 2nd Generation Testosterone (LN 2P13) reagent insert and the ARCHITECT SHBG (LN 8K26) reagent insert were included in the study.

The data from this study are summarized in the following tables.

| SHBG nmol/L                                 |     |        |                              |                               | Testosterone nmol/L [ng/dL] |                              |                               |
|---|-----|--------|------------------------------|-------------------------------|-----------------------------|------------------------------|-------------------------------|
| Category                                    | N   | Median | 2.5 <sup>th</sup> Percentile | 97.5 <sup>th</sup> Percentile | Median                      | 2.5 <sup>th</sup> Percentile | 97.5 <sup>th</sup> Percentile |
| Males (21-49 years of age)                  | 163 | 31.1   | 16.2                         | 68.5                          | 15.33<br>[442.07]           | 8.76<br>[252.73]             | 27.85<br>[803.24]             |
| Males (≥ 50 years of age)                   | 144 | 35.3   | 13.7                         | 69.9                          | 14.42<br>[415.85]           | 8.58<br>[247.50]             | 23.37<br>[674.13]             |
| Females (Premenopausal, 21-49 years of age) | 174 | 48.6   | 14.7                         | 122.5                         | 1.05<br>[30.43]             | 0.52<br>[14.92]              | 1.72<br>[49.56]               |
| Females (Postmenopausal, ≥ 50 years of age) | 175 | 49.9   | 16.7                         | 124.4                         | 0.76<br>[21.83]             | 0.46<br>[13.34]              | 1.18<br>[33.90]               |

The % FTI or % FAI values for the different groups are summarized in the following table.

| % FTI or % FAI                              |     |            |                                  |                                   |
|---|-----|------------|----------------------------------|-----------------------------------|
| Category                                    | N   | Median (%) | 2.5 <sup>th</sup> Percentile (%) | 97.5 <sup>th</sup> Percentile (%) |
| Males (21-49 years of age)                  | 163 | 46.6       | 24.5                             | 113.3                             |
| Males (≥ 50 years of age)                   | 144 | 40.7       | 19.3                             | 118.4                             |
| Females (Premenopausal, 21-49 years of age) | 174 | 2.0        | 0.7                              | 8.7                               |
| Females (Postmenopausal, ≥ 50 years of age) | 175 | 1.5        | 0.5                              | 4.7                               |

**Conclusion:**

The submission is for a labeling change for the %FTI or %FAI Expected Values only. The risk analysis was performed and there is no change in the performance of the previously cleared assay. The performance data provided in K120009 still apply.

The ARCHITECT 2nd Generation Testosterone assay (LN 2P13) is substantially equivalent to the predicate device because the proposed labeling change does not alter the intended use, indications for use, or the fundamental scientific technology of the predicate device.

Furthermore, the residual risk is low because the identified and verified control measures eliminate or reduce the potential effects of failure.

Both ARCHITECT 2nd Generation Testosterone and ARCHITECT SHBG (K152185) labeling will be updated to include the %FTI or %FAI expected values generated using these assays.