July 20, 2018

Monobind Inc.
Anthony Shatola
Quality Director
100 North Pointe Drive
Lake Forest, CA 92630

Re: K181017
Trade/Device Name: Free Testosterone AccuBind ELISA Test System
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I, reserved
Product Code: CDZ
Dated: June 18, 2018
Received: June 19, 2018

Dear Anthony Shatola:

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 Part 801 and Part 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
k181017

Device Name
Free Testosterone AccuBind® ELISA Test System

Indications for Use *(Describe)*
The Free Testosterone AccuBind® ELISA Test System is an Enzyme Immunoassay (EIA) for the quantitative measurement of free testosterone in human serum. Measurement of free testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, impotence in males and in females; hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and adrogenital 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.

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510(k) Summary

1. Submitted by: Monobind Inc.
   Address: 100 North Pointe Drive
   Lake Forest, CA 92630, USA
   Phone: 949-951-2665
   Fax: 949-951-3539
   Website: www.monobind.com
   Company Contact: Anthony Shatola, Quality Director
   Date: July 12, 2018

2. Product Trade Name: Free Testosterone AccuBind® ELISA Test system

   FDA Submission Number: k181017

   Classification Name: Radioimmunoassay,testosterone and dihydrotestosterone

   Product Code: CDZ

   Classification: Class I, Reserved

   Regulation Number / Panel: 862.1680 / Clinical Chemistry

3. Predicate Device: EiAsy Free Testosterone EIA
   Company Name: Diagnostic Biochem Canada, Inc.
   510(k) Number: k030730

A. Test Principle:

Monobind Inc. Free Testosterone test system uses a competitive enzyme immunoassay. The essential reagents required for a solid phase enzyme immunoassay include immobilized antibody, enzyme-antigen conjugate and native antigen. Upon mixing immobilized antibody, enzyme-antigen conjugate and a serum containing the native antigen, a competition reaction results between the native antigen and the enzyme-antigen conjugate for a limited number of insolubilized binding sites. After equilibrium is attained, the antibody-bound fraction is separated from unbound antigen by decantation or aspiration. The enzyme activity in the antibody-bound fraction is inversely proportional to the native antigen concentration. By utilizing several different serum references of known antigen concentration, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained. The serum calibrators are prepared in human serum matrix. The enzyme-antigen conjugate is labelled with horseradish peroxidase (HRP) and the substrate reagent contains tetramethylbenzidine (TMB), a blue color is produced. The reaction is stopped with addition of an acid and a yellow color is developed. The plate is read in a microtiter plate reader at 450nm.

B. Kit Description:

The kit consists of seven (7) vials of serum reference calibrators for Free Testosterone with two (2) controls (one low and one high); one (1) vial of Testosterone (Analog)-horseradish peroxidase (HRP) conjugate in a protein stabilizing matrix; one 96-well testosterone antibody-coated microplate; one (1) vial of concentrated wash solution; two (2) vials for tetramethylbenzidine (TMB) substrate solution preparation; and one (1) vial of stop reaction solution.

C. Indications for Use:

The Free Testosterone AccuBind® ELISA Test System is an Enzyme Immunoassay (EIA) for the quantitative measurement of free testosterone in human serum. Measurement of free testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, impotence in males and in females; hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and adrogenital syndromes.

Comparison with Predicate (EiAsy Free Testosterone EIA):

Similarities and Differences

	Predicate	*Monobind*
Intended Use	The direct quantitative determination of Free Testosterone by enzyme immunoassay in human serum	Same
Antibody	Utilizes a highly specific rabbit polyclonal antibody at a low binding capacity	Same
Detection Method	Microplate colorimetric reader	Same
Test Principle	Competitive Enzyme Immunoassay	Same
Sample Type	Human Serum	Same
Key Reagents		
Calibrators	Six (6) vials containing testosterone in human serum with preservative	Seven (7) vials containing testosterone in human serum with preservative
Control	Two (2) vials containing testosterone in human serum	Three (3) vials containing testosterone in human serum
Calibrator / Control Matrix	Human Serum	Same
HRP conjugate	Testosterone-HRP conjugate in buffer	Same
Wash Buffer Concentrate	Concentrated (10x) buffer with preservatives	Same
TMB Substrate	One vial containing tetramethylbenzidine and hydrogen peroxide in buffer	Two (2) vials: one containing tetramethylbenzidine, one containing hydrogen peroxide
Microplate	Antibody coated plate	Same
Specimen treatment	Direct system; no specimen pretreatment necessary	Same
Measuring range	0.018-60 pg/ml	0.11-60 pg/ml
Expected Range of values (pg/ml)	Males / 20-39: 9.1-32.2 Males / 40-59: 5.7-30.7 Males / ≥60: 5.9-27.0 Females / 20-39: 0.1-6.3 Females / 40-59: 0.3-5.0 Females / ≥60: 0.5-3.9	Males / 20-39: 9.2-34.6 Males / 40-59: 6.1-30.3 Males / ≥60: 6.1-27.9 Females / 20-39: 0.2-6.1 Females / 40-59: 0.3-4.4 Females / ≥60: 0.5-3.4

Test Summary

1. Analytical Performance

   a. Precision

   This study was conducted during 20 days of testing. The human serum and control samples were tested in duplicate, two times per day for a total of 80 measurements per sample. Three (3) different reagent lots, three (3) serum pools, and three (3) controls were used for the study (low, medium, and high concentration). The results of a representative lot are shown below:

Lot 1 N=32	Mean (pg/ml)	Within-Run		Total	
		SD	CV	SD	CV
Control 1	2.51	0.09	3.7%	0.20	7.8%
Control 2	10.98	0.40	3.6%	0.96	8.7%
Control 3	22.72	0.83	3.6%	2.18	9.6%
Serum 1	0.98	0.06	5.9%	0.12	12.4%
Serum 2	4.53	0.26	5.7%	0.36	8.0%
Serum 3	53.62	4.24	7.9%	4.32	8.1%

The results of the combined lot precision are shown below:

	Mean Value (pg/ml)	Within-Run Precision		Within-Kit Precision		Total Precision (n=80)	
		SD	CV%	SD	CV%	SD	CV%
Control 1	2.48	0.11	4.57	0.20	8.20	0.21	8.51
Control 2	11.04	0.47	4.23	0.84	2.60	0.87	8.00
Control 3	23.24	1.00	4.31	1.80	7.73	1.83	7.95
Patient 1	0.97	0.05	4.88	0.09	9.14	0.08	9.43
Patient 2	4.62	0.23	4.88	0.32	6.89	0.33	7.20
Patient 3	54.66	3.25	5.95	3.92	7.17	4.13	7.55

b. Linearity

Sample preparations of 11 concentrations were prepared (0.10-64.91 pg/mL) and assayed per CLSI EP06-A guidance, Evaluation of the Linearity of Quantitative Measurement Procedures. The linear regression obtained is as follows: $y=1.0149x-0.6028$, $R^2=0.9888$

c. Recovery

A study was performed to evaluate the recovery of the test system. Five serum samples containing different levels of endogenous testosterone were spiked with known concentrations of testosterone throughout the measuring range. The samples were measured in replicates of three and the average concentration was compared against the expected value. The recovery results are summarized below:

Sample	*Endogenous Concentration (pg/ml)*	*Average % Recovery*
Patient Sample #1	0.57	100.2%
Patient Sample #2	0.24	102.4%
Patient Sample #3	5.65	98.7%
Patient Sample #4	0.91	104.0%
Patient Sample #5	0.05	105.2%

d. Reagent Stability/Sample Stability

Real time stability studies are conducted to determine the reagent and kit shelf life (expiration date). Expiration date of the Monobind Free Testosterone AccuBind® ELISA Test System is determined by results of shelf studies and is based on the reagent that has the shorter assigned expiration date.

1. The long term stability for kit reagents stored at 2-8 °C is 2 years from the manufacturing date.
2. Open vial, Free Testosterone Calibrator and controls, Free Testosterone Enzyme Reagent stability determination

Condition	*Stability*	*Storage Temperature*
Open Kit Stability	61 days	2-8 °C
Free Testosterone Calibrators	61 days	2-8 °C
Free Testosterone Controls	61 days	2-8 °C
Free Testo Enzyme Reagent	61 days	2-8 °C
TMB Substrate (A&B)	61 days	2-8 °C
Antibody Coated Plate	61 days	2-8 °C

Sample Stability

Condition	*Stability*	*Storage Temperature*
Serum Sample	61 days	2-8 °C
Frozen Serum Sample	31 days	-20 °C

e. Expected Reference Values

The reference range was established according to literature and verified utilizing 261 male and female serum samples. The reference range was calculated using CLSI C28-A3 as a guide. The following table indicates the summary of the results.

Population	N	Reference Range (pg/ml)
Male / 20-39	45	9.2-34.6
Male / 40-59	43	6.1-30.3
Male / ≥60	43	6.1-27.9
Female / 20-39	44	0.2-6.1
Female / 40-59	42	0.3-4.4
Female / ≥60	44	0.5-3.4

f. Detection Limits

The LOB (limit of the blank), the LOD (limit of detection) and the LOQ (limit of quantitation) were determined in accordance with CLSI EP 17-A guideline, Protocols for Determination of Limits of Detection).

Limit of the Blank (LoB)	*Limit of Detection (LoD)*	*Limit of Quantitation (LoQ)*
0.0295 pg/ml	0.0519 pg/ml	0.0519 pg/ml

g. Cross Reactivity

Cross reactivity was determined by testing those compounds most likely to interfere with the Monobind Free Testosterone ELISA Test System. The specificity of the assay was determined in accordance with CLSI EP07-A2. Cross-reactivity was determined using the following equation: observed value - unspiked value/ concentration of cross-reactant x100%. Significant cross reactivity is defined as > 10% difference. The results of the cross-reactivity study are as follows.

		Male Serum Spiked Samples		Blank Serum Spiked Samples	
Sample	Conc. (ng/ml)	Conc (pg/ml)	Cross Reactivity	Conc. (pg/ml)	Cross Reactivity
Base Pool	0	7.408	-	0	
11-Deoxycortisol	1000	7.269	0.000%	0.000	ND
11-KetoTestosterone	10	72.139	0.647%	51.855	0.519%
11β-Hydroxytestosterone	100	72.815	0.065%	54.000	0.054%
17α-ethynyl estradiol	1000	7.351	0.000%	0.000	ND
17α-Estradiol	1000	7.282	0.000%	0.153	0.000%
17β-Estradiol	100	7.363	0.000%	0.000	ND
17-Hydroxypregnenolone	1000	7.35	0.000%	0.000	ND
17-Hydroxprogesterone	10	7.969	0.000%	1.012	0.000%
3-EstriolGluc	1000	7.825	0.000%	0.000	ND
3-EstriolSul	1000	11.729	0.000%	0.000	ND
3β-Androstanediol	500	7.917	0.000%	0.000	ND
5α-Dihydrotestosterone	100	60.975	0.054%	42.382	0.042%
Aldosterone	8000	12.80	0.000%	4.919	0.000%
Amitriptyl HCl	1000	7.301	0.000%	0.000	ND
Androsterone	1000	8.061	0.000%	0.000	ND
Andronstenedione	1000	50.552	0.004%	19.248	0.002%
Clomiphene Citrate	1000	7.263	0.000%	0.000	ND
Corsticosterone	1000	10.099	0.000%	0.777	0.000%
Corstisone	1000	9.90	0.000%	0.478	0.000%
Cortisol	1000	7.316	0.000%	0.298	0.000%
Cyproteroneacetate	1000	10.70	0.000%	0.000	ND
D-5-Androstene-3β,17β-diol	1000	7.782	0.000%	0.000	ND
Danazol	1000	12.30	0.000%	0.000	ND
DHEA	100000	7.311	0.000%	7.457	0.000%
DHEA-S	1000	7.45	0.000%	0.238	0.000%
Desogestrel	100	7.436	0.000%	0.000	ND
Dexamethasone	1000	7.381	0.000%	0.000	ND
Epistestosterone	1000	21.612	0.001%	8.215	0.001%
Estriol	1000	7.368	0.000%	0.122	0.000%
Estrone	1000	7.679	0.000%	0.036	0.000%
Ethisterone	1000	8.597	0.000%	0.003	0.000%

Sample	Conc. (ng/ml)	Conc (pg/ml)	Cross Reactivity	Conc. (pg/ml)	Cross Reactivity
Ethynodiol	1000	8.042	0.000%	0.114	0.000%
Ethynodioldiacetate	50	7.563	0.000%	0.000	ND
Flunisolide	1000	7.456	0.000%	0.000	ND
Fluoxymesterone	1000	7.450	0.000%	0.000	ND
Lynestrol	1000	7.395	0.000%	0.000	ND
Medoxyprogesterone acetate	1000	7.426	0.000%	0.000	ND
Methyl Testosterone	100	7.163	0.000%	0.000	ND
Mestranol	1000	7.338	0.000%	0.000	ND
Norethindrone	50	7.541	0.000%	0.000	ND
Norethinodroneacetate	50	7.428	0.000%	0.000	ND
Norgestimate	1000	7.478	0.000%	0.000	ND
Norgestrel (Levonorgestrel)	50	7.463	0.000%	0.000	ND
Norethynodrel	50	7.544	0.000%	0.000	ND
Oxymetholone	100	7.401	0.000%	0.000	ND
Prednisolone	1000	7.828	0.000%	0.000	ND
Prednisone	800	10.442	0.000%	0.966	0.000%
Progesterone	1000	11.025	0.000%	0.248	0.000%
Salbutamol	1000	8.026	0.000%	0.000	ND
Spironolactone	1000	7.310	0.000%	0.112	0.000%
Stanozolol	1000	7.442	0.000%	0.081	0.000%
Testosteroneenanthate	100	7.304	0.000%	0.044	0.000%
Testosterone SO4	1000	75.970	0.004%	28.182	0.003%
Testosterone Propionate	1000	9.589	0.000%	1.008	0.000%
Triamcinolone	50	7.544	0.000%	0.043	0.000%

An additional study was performed to evaluate the cross-reactivity effects of testosterone cypionate and testosterone undecanoate. Aliquots from pool of human serum with a free testosterone concentration of 38.4 pg/mL were spiked with 12 ng/mL of testosterone cypionate and testosterone undecanoate. Cross-reactivity was determined using the following equation: observed value - unspiked value/ concentration of cross-reactant x100%. Significant cross-reactivity is defined as > 10% difference. The results are summarized in the chart below:

Sample	Conc. (ng/ml)	Conc (pg/ml)	Cross Reactivity	Conc. (pg/ml)	Cross Reactivity
TestosteroneCypionate	12	38.685	0.002%	0.021	0.000%
Testosterone Undecanoate	12	38.262	-0.001%	0.015	-0.001%

3. Method Comparison Studies

Tests were conducted for comparison between the Free Testosterone ELISA Test System and the predicate assay, EiAsy Free Testosterone EIA. The free testosterone concentrations of 137 samples ranging from 0.11-59.63 pg/ml were compared. Comparison of the Monobind Free Testosterone AccuBind® ELISA Test System (new device) and the DBC EiAsy Free Testosterone EIA (predicate) show the following results:

Method	*Least Square Regression Analysis*	*Correlation Coefficient*
This Method (y)	y= 1.017x - 0.244	0.997
Reference (x)		

4. Interferences

Using CLSI-A2 Interference Testing in Clinical Chemistry as a guide, potential interferents were tested utilizing charcoal-stripped human serum spiked with known concentrations of interferent.

The following results of % binding values even at higher than normal interferent levels indicate that there is no significant binding of the free testosterone-HRP conjugate.

Substance	Highest concentration at which no significant interference was observed
Acetaminophen	20 mg/dl
Acetylcysteine	150 mg/dl
Ascorbic Acid	6 mg/dl
Bilirubin Conjugated	15 mg/dl
Bilirubin Unconjugated	20 mg/dl
Biotin	100 ng/ml
Caffeine	6 mg/dl
Cholesterol	503 mg/dl
Creatine	30 mg/dl
Dextran	5000 mg/dl
Digoxin	6.1 ng/ml
Doxycycline	50 mg/L
Erythromycin	6 mg/dl
Gentamicin	1 mg/dl
HAMA	440 ng/ml
Heparin	3 U/ml
Hemoglobin	500 mg/dl
Human Serum Albumin	2.5 g/dl
Ibuprofen	50 mg/dl
Immunoglobulin G	4 g/dl
Levodopa	20 mg/L
Lidocaine	1.2 mg/dl
Lipemia (glycerides)	1000 mg/dl

Substance	Highest concentration at which no significant interference was observed
Methyldopa	20 mg/L
Nicotine	0.1 mg/dl
Phenobarbital	15 mg/dl
Protein: Total	10.5 g/dl
Rheumatoid Factor	1110 IU/ml
Salicylic Acid	60 mg/dl
SHBG	200 µg/ml
Triglycerides	900 mg/dl
Urea	500 mg/dl

ConcludingStatement:

Taken together, the performance characteristics, comparison studies with a predicate device and acceptable statistical performance studies in this 510(k) Class I, reserved submission demonstrates that the Monobind Free Testosterone AccuBind® ELISA Test System is safe and effective for its intended use and is substantially equivalent to the predicate device.