April 15, 2026

Immunodiagnostics Systems Limited
Mick Henderson
Group RA Manager
10 Didcot Way
Boldon Business Park
Boldon
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NE35 9PD
United Kingdom

Re: K252728
Trade/Device Name: IDS-iSYS Total Testosterone
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone Test System
Regulatory Class: Class I, reserved
Product Code: CDZ
Dated: March 11, 2026
Received: March 11, 2026

Dear Mick Henderson:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry
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OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252728

Device Name
IDS-iSYS Total Testosterone

Indications for Use *(Describe)*

The IDS-iSYS Total Testosterone assay is an in vitro diagnostic device intended for the quantitative determination of testosterone in human serum or plasma on the IDS system.

Measurement 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.

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510(k) SUMMARY

510k Number K252728

Introduction According to the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter

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Date prepared: 09th April 2026

Device Name

Proprietary names:	IDS-iSYS Total Testosterone
Common names:	As above
Classification:	21 CFR 862.1680 –Testosterone Test System Class I, reserved
Product Code:	CDZ

Predicate Device Elecsys Testosterone II (k211685)

Device Description The IDS-iSYS Total Testosterone assay consists of a reagent cartridge. The reagent cartridge contains multiple reagents:

- **MP3**: Magnetic particles coated with Streptavidin in a PBS Pluronic buffer with sodium azide as preservative (<0.1 %), 1 bottle, 2.5 mL
- **CONJ**: Testosterone linked to mouse protein labelled with an acridinium ester derivative, in a phosphate buffer with ProClin® 300 as preservative (<0.0015%), 1 bottle, 3.5 mL
- **Ab-BIOT**: Anti-Testosterone sheep monoclonal antibody labelled with biotin, in a phosphate buffer containing bovine and sheep protein with ProClin® 300 as preservative (<0.0015%), 1 bottle, 11.5 mL
- **BUF**: MES buffer containing BSA (0.1%), 4-Cloro-m-cresolo (0.1 mg/mL), Tween 20 (0.055%) and ProClin® 300 (0.0025%). 1 bottle, 11.5 mL
- **Cal A**: Human serum matrix containing human Testosterone with <0.1 % sodium azide and ProClin® 300 (0.0025%) as preservative. 1.0 mL per bottle
- **Cal B**: Human serum matrix containing human Testosterone with <0.1 % sodium azide and ProClin® 300 (0.0025%) as preservative. 1.0 mL per bottle

Indications for Use

The IDS-iSYS Total Testosterone assay is an *in vitro* diagnostic device intended for the quantitative determination of testosterone in human serum or plasma on the IDS system.

Measurement 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.

Conditions for use For in vitro diagnostic use only.
Rx Only

Special instrument Requirements:

IDS-iSYS Multi-Discipline Automated System (k091849)

Comparison Tables

Similarities compared to the chosen (FDA cleared; marketed) predicate device (k211685)

Assay Performance	**Predicate Device Elecsys Testosterone II (K211685)**	**Candidate Device IDS-iSYS Total Testosterone**
Intended Use	quantitative determination of Testosterone	Same
Test Principle	Competitive immunoassay	Same
Sample Type	Human serum or plasma	Same
Antibody	Biotinylated monoclonal anti-testosterone antibody (sheep)	Same

Differences compared to the chosen (FDA cleared; marketed) predicate device (k211685)

Assay Performance	**Predicate Device Elecsys Testosterone II (K211685)**	**Candidate Device IDS-iSYS Total Testosterone**
Detection Method	electrochemiluminescence	Chemiluminescence
Measuring range	2.50-1500 ng/dL	14 to 1500 ng/dL
Expected Range of Values	Females, 20 – 49 8.4 – 48.1 Females, ≥ 50 years 2.9 – 40.8 Males, 20 – 49 249 – 836 Males, ≥ 50 years 193 - 740	Females, 21 - 49 years <14 – 51 Females, ≥ 50 years <14 – 48 Males, 21 - 49 years 213 – 818 Males, ≥ 50 years 180 - 711

Performance Characteristics

Analytical Limits at Low levels

The limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) were determined following the guidance of CLSI EP17-A, "Protocols for Determination of Limits of Detection and Limits of Quantitation" with 2 IDS Total Testosterone kit lots. LoB and LoD were determined with 60 replicates of 4 blank samples and 6 low concentration samples per reagent lot. LoQ was determined with 105 replicates of 7 low concentration samples per reagent lot. The design criteria of the limit of quantitation (LoQ) was ≤ 20 ng/dL. The LoQ is set as the lowest concentration of analyte that can be reproducibly measured with an intermediate precision coefficient of variation of ≤ 20 %.

Sensitivity	Concentration (ng/dL)
Limit of Blank (LoB)	4
Limit of Detection (LoD)	8
Limit of Quantitation (LoQ)	14

Precision (Repeatability/Reproducibility)

Precision studies were performed with guidance from CLSI EP05 A3 "Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline".

Single Site Precision

A total of 8 serum samples were measured using 1 reagent lot, in duplicate, twice a day for 20 days on 1 IDS system, for a total of 80 replicates per sample to assess the repeatability.

Sample ID	N	Mean (ng/dL)	Repeatability		Within Laboratory	
			SD	CV%	SD	CV%
S11	80	42.5	2.2	5.2%	4.3	10.2%
S3	80	73.1	3.5	4.8%	5.5	7.5%
S4	80	125.3	3.9	3.1%	7.3	5.9%
S5	80	179.9	5.2	2.9%	9.6	5.3%
S6	80	401.6	7.6	1.9%	16.4	4.1%
S7	80	588.4	16.5	2.8%	28.2	4.8%
S8	80	1145.7	24.2	2.1%	52.7	4.6%
S9	80	1228.0	27.1	2.2%	45.9	3.7%

Site to Site Precision

A total of 8 serum samples were measured using one reagent lot in 5 replicates, once a day for 5 days on 3 IDS systems by 1 operator per system, for a total of 75 replicates per sample to determine the reproducibility

.Sample ID	N	Mean (ng/dL)	Repeatability SD	Repeatability CV	Between Site SD	Between Site CV	Reproducibility SD	Reproducibility CV
S11	75	43.8	3.2	7.3%	0.0	0.0%	4.0	9.2%
S3	75	79.3	4.4	5.5%	4.6	5.8%	8.8	11.1%
S4	75	140.5	5.4	3.8%	6.7	4.7%	14.2	10.1%
S5	75	198.3	8.0	4.1%	9.5	4.8%	16.6	8.4%
S6	75	442.9	9.7	2.2%	22.7	5.1%	33.1	7.5%
S7	75	614.4	23.4	3.8%	36.3	5.9%	52.3	8.5%
S8	75	1167.6	53.6	4.6%	28.8	2.5%	77.5	6.6%
S9	75	1258.7	37.8	3.0%	52.4	4.2%	85.4	6.8%

Lot to Lot Precision

A total of 8 serum samples were tested using three reagents lot in 5 replicates, once a day for 5 days on 1 IDS system by 1 operator per system for a total of 75 replicates per sample to determine the reproducibility.

Sample ID	N	Mean (ng/dL)	Repeatability SD	Repeatability CV	Between Lot SD	Between Lot CV	Reproducibility SD	Reproducibility CV
S11	75	43.4	2.8	6.4%	2.3	5.4%	4.3	10.0%
S3	75	73.6	4.0	5.4%	3.9	5.3%	7.5	10.2%
S4	75	136.8	6.4	4.7%	6.3	4.6%	12.8	9.3%
S5	75	191.4	5.5	2.9%	7.5	3.9%	12.4	6.5%
S6	75	438.2	13.2	3.0%	23.4	5.3%	31.1	7.1%
S7	75	576.8	14.3	2.5%	12.7	2.2%	27.1	4.7%
S8	75	1137.8	40.0	3.5%	29.5	2.6%	57.1	5.0%
S9	75	1206.5	44.0	3.7%	31.4	2.6%	67.1	5.6%

Linearity

Linearity was evaluated based on CLSI EP06 Ed2, “Evaluation of Linearity of Quantitative Measurement Procedures”. For concentration by IDS Total testosterone assay, the measurement procedure shows the linearity between 5 ng/dL and 1578 ng/dL was within the allowable deviation of linearity (ADL) of ≤ ±12.0%, or ≤+/- 20 ng/dL for concentrations below 80 ng/dL.

Analytical Specificity

Cross-reactivity studies were performed in accordance with the CLSI guidance EP07-A3 "Interference testing in clinical chemistry". The study was conducted by spiking the cross-reacting compounds into 2 samples containing approximately 60 and 500 ng/dL concentrations of testosterone. Results are shown in the table below:

Cross Reactant	Cross Reactant Concentration	% Cross Reactivity
11-Ketotestosterone ±	200 ng/mL	4.9%
11-Ketotestosterone ±	100 ng/mL	6.1%
11-β-Hydroxy testosterone ±	50 ng/mL	24.3%
11-β-Hydroxy testosterone ±	25 ng/mL	27.4%
19-Norethisterone	40 ng/mL	0.8%
5α-Androstane-3β,17β-diol	1000 ng/mL	0.1%
5-α-Androstene-3β,17β-diol	1000 ng/mL	0.1%
Androstenedione	100 ng/mL	2.3%
Cortisol	5000 ng/mL	<0.1%
Cortisone	5000 ng/mL	<0.1%
Danazol	1000 ng/mL	<0.1%
Dexamethasone	2000 ng/mL	<0.1%
DHEA	5000 ng/mL	0.1%
DHEA-S	50000 ng/mL	<0.1%
Dihydrotestosterone	500 ng/mL	0.4%
Estradiol	5000 ng/mL	0.1%
Estrone	5000 ng/mL	<0.1%
Ethisterone	1000 ng/mL	0.2%
Norgestrel	1000 ng/mL	0.1%
Prednisolone	5000 ng/mL	<0.1%
Prednisone	5000 ng/mL	<0.1%
Progesterone	5000 ng/mL	<0.1%
Testosterone propionate	100 ng/mL	<0.1%

±A strong interaction with 11-Ketotestosterone and 11β-hydroxy testosterone was found.

Limitations of Use

- A strong interaction with 11-Ketotestosterone and 11β-hydroxytestosterone was found.

The interference testing for IDS Total Testosterone was evaluated following the CLSI EP07-ED3, "Interference Testing in Clinical Chemistry". The potential endogenous interfering agent was evaluated using 4 samples with testosterone concentrations of containing 30, 75, 300 and 1200 ng/dL. No significant interference (≤±10%) was observed when the interfering substances were tested at the specified threshold concentration:

Potentially Interfering Agent	Threshold Concentration
Bilirubin (Conjugated)	40 mg/dL
Bilirubin (Unconjugated)	40 mg/dL
Hemoglobin	1000 mg/dL
Triglycerides	1500 mg/dL

Limitations of Use

- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays [4]. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed.

A study was conducted to evaluate the IDS Total Testosterone susceptibility to biotin interference. Up to 3500 ng/mL of biotin was spiked into serum samples containing three different concentrations of osteocalcin, approximately 40, 700, 300, and 1100 ng/mL. Table below tabulated the %bias for samples containing various concentration of biotin:

	Biotin Conc. (ng/mL)	% Bias from 0 ng/mL of biotin						
		250	350	450	500	750	1000	3500
Testosterone Conc. (ng/dL)	40	-4%	5%	86%	>100%	>100%	>100%	>100%
	70	-1%	4%	52%	Not tested	Not tested	Not tested	>100%
	300	2%	10%	50%	Not tested	Not tested	Not tested	Not tested
	1100	-3%	-1%	14%	>100%	>100%	>100%	>100%

Method Comparison

The IDS Total Testosterone was compared against a commercially available quantitative total testosterone CLIA, following CLSI EP09c, "Method Comparison and Bias Estimation Using Patient Samples". A total of 125 samples, selected to represent a wide range of testosterone concentrations, 14 to 1450 ng/dL, were tested by each method. Passing-Bablok regression analysis was performed on the comparative data:

N	Slope	95 % CI	Intercept (ng/dL)	95 % CI	Corr. Coef. (r)
125	0.96	0.93 to 0.98	1.06	-2.01 to 4.29	1.00

Matrix comparison

The sample matrix comparison studies, based on guidance from CLSI EP35 Ed1 "Assessment of Equivalence for Suitability of Specimen Types for Medical Laboratory Measurement Procedures", were performed to assess the equivalence between serum (serum without additives, serum gel separator tubes (SST)) and plasma (K_2 EDTA, K_3 EDTA, Sodium Heparin and Lithium Heparin) sample matrices in the IDS Total Testosterone assay. A total of 50 matched sample pairs (for SST, K2 EDTA, Li Heparin, and Na Heparin) and 39 pairs for serum and K3 EDTA with concentrations ranging from 16 to 1500 ng/dL, were analyzed with Passing-Bablok regression analysis on the comparative data:

Sample Type	N	Slope	95% CI	Intercept (ng/dL)	95% CI	Corr. Coeff. (r)
SST	50	0.99	0.97 to 1.02	0.42	-6.55 to 3.26	1.00
K_2 EDTA	50	0.99	0.96 to 1.01	-1.25	-7.56 to 4.01	1.00
K_3 EDTA	39	0.99	0.95 to 1.03	-0.49	-6.88 to 3.54	1.00
Li Heparin	50	0.98	0.96 to 1.01	2.36	-0.08 to 15.3	1.00
Na Heparin	50	0.99	0.96 to 1.01	1.94	-2.63 to 8.97	1.00

Expected Values

The following ranges were determined using the IDS Total Testosterone and are provided for information only. The 95% reference interval for apparently healthy adults were calculated by a non-parametric method following guidance from CLSI C28-A3 "Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory".

Population	No. of subjects	Median (ng/mL)	5th to 95th percentile
Females, 21 - 49 years	119	23	<14 - 51
Females, ≥ 50 years	108	22	<14 - 48
Males, 21 - 49 years	266	459	213 - 818
Males, ≥ 50 years	231	402	180 - 711

The above ranges should only be used as information; it is recommended that each laboratory determine its own expected range based upon its own patient population.

Conclusion

The IDS-iSYS Total Testosterone data presented and provided is complete and supports the basis for substantial equivalence to the predicate device.