DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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IMMUNODIAGNOSTIC SYSTEMS LTD.
MICK HENDERSON, REGULATORY AFFAIRS OFFICER
10 DIDCOT WAY, BOLDEN BUSINESS PARK
BOLDON, TYNE & WEAR, NE35 9PD
UNITED KINGDOM

May 17, 2016

Re: K161082
Trade/Device Name: IDS-iSYS 17-OH Progesterone Control Set,
IDS-iSYS 17-OH Progesterone Calibration Verifiers
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: April 15, 2016
Received: April 18, 2016

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 (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)*
k161082

Device Name
IDS-iSYS 17-OH Progesterone Control Set
IDS-iSYS 17-OH Progesterone Calibration Verifiers

Indications for Use *(Describe)*
IDS-iSYS 17-OH Progesterone Control Set

The IDS-iSYS 17-OH Progesterone Control Set is for in vitro diagnostic use, for the quality control of the IDS-iSYS 17-OH Progesterone on the IDS-iSYS Multi-Discipline Automated System.

Rx Only.

IDS-iSYS 17-OH Progesterone Calibration Verifiers

The IDS-iSYS 17-OH Progesterone Calibration Verifiers are an in vitro diagnostic device intended for medical purposes in the quantitative verification of assay calibration and measuring range of the IDS-iSYS 17-OH Progesterone assay, when performed on the IDS-iSYS Multi Discipline Automated System.

Rx Only.

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

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

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Date Prepared: 12th May 2016

Device Name: Proprietary names: IDS-iSYS 17-OH Progesterone Control Set
Model No. IS-5130
IDS-iSYS 17-OH Progesterone
Calibration Verifiers
Model No. IS-5135

Common names: As above

Classification: 21CFR862.1660 (Class I, Reserved)

Product Code: JJX

Device Descriptions: The IDS-iSYS 17-OH Progesterone Control Set consists of Two sets of three vials, 1.0 mL each in liquid form. Human serum containing 17-OH Progesterone and sodium azide as a preservative (<0.1%), with three concentration levels.

The IDS-iSYS 17-OH Progesterone Calibration Verifiers consists of

Four calibration verifier levels in liquid form (two 1.0mL vials for level 0 and one 1.0mL vial for levels 1, 2 & 3).
Human serum containing 17-OH Progesterone and sodium azide as a preservative (<0.1%), with three concentration levels.

Predicate Devices: IDS-iSYS CTX-I (CrossLaps®) Control Set
IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers

Predicates 510(k): k111650

Special Conditions for Use: For in vitro diagnostic use.
Rx Only

Special instrument Requirements: IDS-iSYS Multi-Discipline Automated System (k091849)

Intended Use:

The IDS-iSYS 17-OH Progesterone Control Set is for *in vitro* diagnostic use, for the quality control of the IDS-iSYS 17-OH Progesterone on the IDS-iSYS Multi-Discipline Automated System.

RX Only

The IDS-iSYS 17-OH Progesterone Calibration Verifiers are an *in vitro* diagnostic device intended for medical purposes in the quantitative verification of assay calibration and measuring range of the IDS-iSYS 17-OH Progesterone assay, when performed on the IDS-iSYS Multi Discipline Automated System.

Rx Only.

Comparison with predicate:
17OH-Progesterone Control Set
Similarities and differences compared to the chosen predicate device:-
IDS-iSYS CTX-I (CrossLaps®) Control Set **(**k111650)

Performance	**Predicate Device:** IDS-iSYS CTX-I (CrossLaps®) Control Set **(**k111650)	**Candidate Device:** IDS-iSYS 17-OH Progesterone Control Set
Indications for Use	Used for quality control of	Used for quality control of the

	the IDS-iSYS CTX-I (CrossLaps®) Assay.	IDS-iSYS 17-OH Progesterone Assay.
Analyte Concentrations	CTX-I Low control: 0.2ng/mL. Medium Control: 0.8ng/mL. High Control: 2ng/mL.	17-OH Progesterone Low control: 2.0ng/mL. Medium Control: 5.0ng/mL. High Control: 10.0ng/mL.
Analyzer System	IDS-iSYS Multi-Discipline Automated System	Same
Stability and storage	2-8°C – unopened until expiration date After opening: stable for 28 days at 4°C On board stability: 3 hours	Same After opening: stable for 49 days at 2-8°C On board stability: 4 hours
Matrix	Liquid, phosphate bovine serum albumin	Human serum

17OH-Progesterone Calibration Verifiers

Similarities and differences compared to the chosen predicate device:-

IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers **(**k111650)

Performance	**Predicate Device:** IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers **(**k111650)	**Candidate Device:** IDS-iSYS 17-OH Progesterone Calibration Verifiers
Indications for Use	Used for the quantitative verification of calibration of the IDS-iSYS CTX-I (CrossLaps®) assay.	Used for the quantitative verification of calibration of the IDS-iSYS 17-OH Progesterone assay.
Levels	Levels 0, 1, 2 & 3	Same
Matrix	Liquid, phosphate bovine serum albumin	Human serum
Stability and Storage	2-8°C – unopened until expiration date On board stability: Single Use – use then discard	Same Same

Analyte Concentrations	CTX-I 0.0ng/mL, 0.6ng/mL, 3.0ng/mL and 5.0ng/mL	17-OHProgesterone Cal Ver 0: Undetectable Cal Ver 1: 2.0ng/mL Cal Ver 2: 8.0 ng/mL Cal Ver 3: 17.0ng/mL
Analyzer System	IDS-iSYS Multi-Discipline Automated System	Same

Performance Characteristics

IDS-iSYS 17-OH Progesterone Control Set

Value Assignment

Each control level is tested on three IDS-iSYS Multi Discipline Automated Systems with a minimum of 21runs using cartridge batches available tested in triplicate. Control solutions are prepared gravimetrically from an intermediate stock solution and concentrations are confirmed by immunologic analysis using IDS-iSYS 17-OH Progesterone assay on IDS-iSYS Multi Discipline Automated System. In the value assignment process, controls were calibrated using a master calibrator to generate a master curve. The assigned target value of each control level is defined as the mean of all the runs for the IDS-iSYS 17-OH Progesterone assay and analyzer. The following are the expected values for each level of control: 2.0 ng/mL, 5.0 ng/mL and 10.0 ng/mL.

Stability

Closed vial:

For the real time closed vial testing, three lots of controls were stored at 4°C.

Each control material will be tested in pentaplicate in 2 month intervals for up to a minimum of 15 months. Each control vial tested will be compared back to reference control material stored at -20°C. Controls must be within acceptance criteria defined as below:

- mean concentration must be within QC ranges (as stated in the Certificate of Analysis)
- precision: CV ≤ 10% for low concentration - ≤ 8% for middle and high concentration

To date, accelerated stability studies performed according to the CLSI guideline EP25-A (Evaluation of stability of In Vitro Diagnostic Reagents) support a stability claim of 9 months when stored at 2-8°C.

Real time stability studies in accordance with the CLSI guideline EP25-A (Evaluation of stability of In Vitro Diagnostic Reagents) to support the above claims are ongoing.

Open Vial:

Open vial (in-use) stability of controls were performed at 4°C and tested against unopened vials of control material stored at 4°C. Controls were tested in duplicate at the time points stated in the stability protocol. Percent recoveries of each material

were within the acceptance criteria of 10% of the reference material concentration. Data supports the open vial stability claim of 49 days when stored at 2-8°C.

On-Board:
On-board stability studies were performed using three batches of controls using three IDS-iSYS instruments. Controls were tested at time 0, 2 hours, 4 hours, 6 hours and 8 hours and compared to a reference material run at time 0. The on board stability data supports the claimed on-board stability of 4 hours.

IDS-iSYS 17-OH Progesterone Calibration Verifiers

Value Assignment

Each calibration verifier level is tested on three IDS-iSYS Multi Discipline Automated Systems with a minimum of five runs for each cartridge batch tested in triplicate. Calibration Verifiers solutions are prepared gravimetrically from an intermediate stock solution and concentrations are confirmed by immunologic analysis using IDS-iSYS 17-OH Progesterone assay on IDS-iSYS Multi Discipline Automated System. In the value assignment process, calibration verifiers were calibrated using a master calibrator to generate a master curve. The assigned target value of each calibration verifier level is defined as the mean of all the runs for the IDS-iSYS 17-OH Progesterone assay and analyzer. The following are the expected values for each level of calibration verifier: 2.0 ng/mL, 8.0 ng/mL, and 17.0 ng/mL.

Stability

For the real time closed vial testing, three lots of calibration verifiers will be stored at 4°C. Each calibration verifier will be tested in pentaplicate in 2 month intervals for up to a minimum of 15 months.

Calibration verifiers must be within acceptance criteria defined as below:

- mean concentration must be within QC ranges (as stated in the Certificate of Analysis)
- precision: CV $\leq$ 10% for low concentration - $\leq$ 8% for middle and high concentration

To date, accelerated stability studies performed according to the CLSI guideline EP25-A (Evaluation of stability of In Vitro Diagnostic Reagents) support a stability claim of 9 months when stored at 2-8°C.

Real time stability studies in accordance with the CLSI guideline EP25-A (Evaluation of stability of In Vitro Diagnostic Reagents) to support the above claims are ongoing.

On-Board:
On-board stability studies were performed using three batches of calibration verifiers using three IDS-iSYS instruments. Calibration verifiers were tested at time 0, 2 hours,

4 hours, 6 hours and 8 hours and compared to a reference material run at time 0. The on board stability data supports the claimed on-board stability of 4 hours.

Proposed Labeling
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.