



10903 New Hampshire Avenue
Silver Spring, MD 20993

IMMUNODIAGNOSTIC SYSTEMS LTD.

c/o Mick Fenton
10 Didcot Way
Bolden Business Park
Baldon, Tyne & Wear
United Kingdom NE35 9PD

FEB 14 2012

Re: k111938

Trade Name: IDS-iSYS IGFBP-3 Calibration Verifiers, IDS-iSYS IGFBP-3 Control
Set, IDS-iSYS hGH Calibration Verifiers

Regulation Number: 21 CFR §862.1660

Regulation Name: Quality control material (assayed and unassayed)

Regulatory Class: Class I, reserved

Product Codes: JJX

Dated: January 20, 20112

Received: January 23, 2012

Dear Mr. Fenton:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

K number **K**

Device **IDS-iSYS IGFBP-3 Calibration Verifiers**

The IDS-iSYS IGFBP-3 Calibration Verifier is a device intended for medical purposes for use in the quantitative verification of calibration of the IDS-iSYS IGFBP-3 Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 12111938

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INDICATIONS FOR USE

K number **K**

Device **IDS-iSYS hGH Calibration Verifiers**

The IDS-iSYS hGH Calibration Verifier is a device intended for medical purposes for use in the quantitative verification of calibration of the hGH Assay (IDS-iSYS hGH) when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



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