



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 18, 2013

Immunodiagnostic Systems Ltd.
C/O Mick Fenton
10 DIDCOT WAY,
BOLDON BUSINESS PARK,
BOLDON, TYNE AND WEAR
UNITED KINGDOM NE35 9PD

Re: K123253

Trade/Device Name: IDS iSYS 1,25 Dihydroxy Vitamin D
IDS iSYS 1,25 Dihydroxy Vitamin D Control Set
IDS iSYS 1,25 Dihydroxy Vitamin D Calibration Verifier

Regulation Number: 21 CFR 862.1825

Regulation Name: Vitamin D test system

Regulatory Class: II

Product Code: MRG, JJX

Dated: June 06, 2013

Received: June 11, 2013

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. 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); 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 regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Carol C. Benson -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 Form

510(k) Number (if known): k123253

Device Name: IDS iSYS 1,25 Dihydroxy Vitamin D
IDS iSYS 1,25 Dihydroxy Vitamin D Control Set
IDS iSYS 1,25 Dihydroxy Vitamin D Calibration Verifiers

Indications for Use: The IDS-iSYS 1,25 Dihydroxy Vitamin D assay is intended for the determination of 1,25 dihydroxyvitamin D levels in serum and plasma on the IDS-iSYS Multi-Discipline Automated System. Results of the 1,25 Dihydroxy Vitamin D are used in the assessment of vitamin D sufficiency.

The IDS-iSYS 1,25 Dihydroxy Vitamin D Control Set is used for quality control of the IDS-iSYS 1,25 Dihydroxy Vitamin D assay on the IDS-iSYS Multi-Discipline Automated System

The IDS-iSYS 1,25 Dihydroxy Vitamin D Calibration Verifier is a device intended for medical purposes for use in the quantitative verification of calibration of the IDS-iSYS 1,25 Dihydroxy Vitamin D assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung  Chan -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k123253