De: Immunodiagnostic Systems ltd.
c/o Mick Fenton
Regulator Affairs Officer
10 Didcot way
Bolden Business Park
Boldon, Tyne & Wear, NE35 9PD, UK

Re: k111650
Trade Name: IDS-iSYS CTX-1 (Crosslaps®) Calibration Verifiers, IDS-iSYS 25
Hydroxy Vitamin D Calibration Verifiers, and IDS-iSYS CTX-1
(Crosslaps®) Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJX
Dated: June 8, 2011
Received: June 13, 2011

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
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
INDICATIONS FOR USE

K number K111650

Device IDS-iSYS CTX-I (Crosslaps) Control Set

The IDS-iSYS CTX-I (CrossLaps) Control Set is intended for medical purposes for use in the IDS-iSYS CTX-I (Crosslaps) Assay on the IDS-iSYS Multi-Discipline Automated Analyser to monitor the accuracy and quality of the IDS-iSYS CTX-I (Crosslaps) Assay.

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (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) ___ ___ ___ ___ ___ ___
INDICATIONS FOR USE

K number  K111650

Device    IDS-iSYS 25-Hydroxy Vitamin D Calibration Verifiers

The IDS-iSYS 25-Hydroxy Vitamin D Calibration Verifiers are intended for use in the quantitative verification of calibration and assay range of the IDS-iSYS 25-Hydroxy Vitamin D Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Prescription Use    X
(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) ________________

Page 2 of 3
INDICATIONS FOR USE

K number K111650

Device IDS-iSYS CTX-I (Crosslaps) Calibration Verifiers

The IDS-iSYS CTX-I (CrossLaps) Calibration Verifier is a device intended for medical purposes for use in the quantitative verification of calibration and assay range of the IDS-iSYS CTX-I (CrossLaps®) Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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)