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

April 24, 2013

Nipro Diagnostics, Inc.
C/O Karen DeVincent
2400 NW 55th Court
FORT LAUDERDALE FL 33309

Re: K120989
Trade/Device Name: TRUE METRIX™ Self Monitoring Blood Glucose System
TRUE METRIX PRO™ Professional Monitoring Blood Glucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: April 16, 2013
Received: April 18, 2013

Dear Ms. DeVincent:

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" (21CFR 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): k120989

Device Name: **TRUE METRIX™ Self Monitoring Blood Glucose System**

Indications for Use:

The **TRUE METRIX™ Self Monitoring Blood Glucose System** is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm. The TRUE METRIX™ Self Monitoring Blood Glucose System is intended to be used by a single person and not be shared.

The TRUE METRIX™ Self Monitoring Blood Glucose System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TRUE METRIX™ Self Monitoring Blood Glucose System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The TRUE METRIX Test Strips are for use with the TRUE METRIX™ Self Monitoring Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm.

The TRUE METRIX Control Solution is for use with the TRUE METRIX Self Monitoring Meter and TRUE METRIX Test Strips to check that the meter and the test strip are working together properly and that the test is performing correctly.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___√___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k120989

Indications for Use Form

510(k) Number (if known): k120989

Device Name: **TRUE METRIX PRO™ Professional Monitoring Blood Glucose System**

Indications for Use:

The **TRUE METRIX PRO Professional Monitoring Blood Glucose System** is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm and venous whole blood.

The TRUE METRIX PRO Professional Monitoring Blood Glucose System is intended for multiple-patient use in professional healthcare settings. Testing is performed outside the body (*in vitro* diagnostic use) as an aid for monitoring the effectiveness of diabetes control. TRUE METRIX PRO Professional Monitoring Blood Glucose System is used only with single-use, auto-disabling lancing devices. The system is not to be used on neonates or for the diagnosis or screening of diabetes mellitus. Alternative site testing can only be performed during steady-state blood glucose conditions.

The TRUE METRIX PRO Test Strips are for use with the TRUE METRIX PRO Professional Monitoring Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm and venous whole blood.

The TRUE METRIX Control Solution is for use with the TRUE METRIX PRO Professional Monitoring Meter and TRUE METRIX PRO Test Strips to check that the meter and test strip are working together properly and that the test is performing correctly.

Prescription Use _√_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __√____ (21 CFR 801 Subpart C)

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

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