



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

August 1, 2014

NIPRO DIAGNOSTICS, INC.  
BETH FOSTER  
REGULATORY AFFAIRS MANAGER  
2400 NW 55TH COURT  
FORT LAUDERDALE FL 33309

Re: K140100

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  
Dated: July 21, 2014  
Received: July 22, 2014

Dear Ms. Beth Foster:

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,

**Courtney H. Lias -S**

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

510(k) Number (if known)

k140100

Device Name

TRUE METRIX Self Monitoring Blood Glucose System

Indications for Use (Describe)

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 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 Self Monitoring 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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

# Stayce Beck -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

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## Indications for Use

510(k) Number (if known)  
k140100

Device Name  
TRUE METRIX PRO Professional Monitoring Blood Glucose System

### Indications for Use (Describe)

The TRUE METRIX PRO Professional 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 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 to monitor the effectiveness of diabetes control. The 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 for neonates or for the diagnosis or screening of diabetes. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

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

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)

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