5. 510(k) Summary

K101633

510(k) Summary

(as required by 21 CFR 807.92)

AUG 27 2010

Submitter: Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454 U.S.A.

Correspondent: Paul W. MacDonald
Chief Quality Assurance and Regulatory Affairs Officer

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Device Name: Nova Max Plus Glucose and β-Ketone Control Solutions

Common Name: Single (Specified) Analyte Controls (Assayed And Unassayed)

Classification: Clinical Chemistry and Clinical Toxicology Devices
Clinical Chemistry

Single (Specified) Analyte Controls (Assayed And Unassayed)
Class I per 21 CFR 862.1660
Nitroprusside, Ketones (Urinary, Non-Quant.)
Class I per 21 CFR 862.1435

Product Codes: JJX, JIN

Predicate Devices: Nova Max Plus Blood Glucose and B-Ketone Monitor System, K091547
Nova Max Blood Glucose Monitor, K070255

Description of the Device:

Intended Use/Indications for Use:

Nova Max Plus Glucose and β-Ketone Control Solutions are intended for use with the Nova Max Family of Monitors (Nova Max, Nova Max Plus, and Nova Max Link), BD Logic and Paradigm Link Monitors, Nova Max Glucose Test Strips, and Nova Max Plus Ketone Test Strips as a quality control check to verify the accuracy of blood Glucose and β-Ketone test results. There are two levels of Nova Max Plus Glucose and β-Ketone Control Solutions (Mid and High).

Nova Max Plus Glucose and β-Ketone Control Solutions are for *in vitro* diagnostic use ONLY (for testing outside the body).

Summary of Technological Characteristics:

The proposed Nova Max Plus Glucose and β- Ketone Control Solutions measures Glucose and β-Ketone electrochemically. The magnitude of the current is proportional to the amount of Glucose or, β-hydroxybutyrate *(β-* Ketone) present in the sample, providing a quantitative measure of Glucose or β-Ketone in whole blood, or control solutions.

Comparison to Predicate Devices:
The proposed Nova Max Plus Glucose and β-Ketone Control solutions use the same fundamental scientific technology and have the same intended use as the control solutions previously cleared in the predicate Nova Max Plus Blood Glucose and β-Ketone Monitor System (K091547), and the predicate Nova Max Blood Glucose Monitor (K070255).

Performance Studies:
The performance of the Nova Max Plus Glucose and β-Ketone control solutions has been studied in the laboratory. Stability studies, precision studies, and equivalency studies have all been performed. All results support the conclusion of substantial equivalence to the currently marketed predicate devices.

Conclusion:
Results of laboratory testing demonstrate that the performance of the Nova Max Plus Glucose and β-Ketone Control Solutions can produce results that are substantially equivalent to results obtained with the previously cleared predicate devices. In addition, the proposed device utilizes the same fundamental scientific technology, and has the same intended use as the previously cleared predicate devices. There are no new concerns for safety and effectiveness that have been shown through testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Nova Biomedical Corporation
c/o Mr. Paul W. MacDonald
Regulatory Affairs Specialist
200 Prospect Street
Waltham, MA 02454

AUG 2 7 2010

Re: k101633
Trade Name: Nova Max Plus Glucose and β-Ketone Control Solutions
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: July 20, 2010
Received: July 21, 2010

Dear Mr. MacDonald:

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

Enclosure

4. Indications for Use

K101633

Indications for Use

510(k) Number: K101633

Device Name: **Nova Max Plus Glucose and β-Ketone Control Solutions**

Indications for Use:

Nova Max Plus Glucose and β-Ketone Control Solutions are intended for use with the Nova Max Family of Monitors (Nova Max, Nova Max Plus, and Nova Max Link), BD Logic and Paradigm Link Monitors, Nova Max Glucose Test Strips, and Nova Max Plus Ketone Test Strips as a quality control check to verify the accuracy of blood Glucose and β-Ketone test results. There are two levels of Nova Max Plus Glucose and β-Ketone Control Solutions (Mid and High).

Nova Max Plus Glucose and β-Ketone Control Solutions are for *in vitro* diagnostic use ONLY (for testing outside the body).

Prescription Use _____ And/Or Over the Counter Use _X_
(21 CFR Part 801 Subpart D) (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 Diagnostic Device Evaluation and Safety (OIVD)

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

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(Updated February 3, 2005)