DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 11, 2017

NOVA BIOMEDICAL CORPORATION
ELIZA WANG
SENIOR REGULATORY AFFAIRS SPECIALIST
200 PROSPECT STREET
WALTHAM MA 02454

Re: K160990
Trade/Device Name: Nova Max Uric Acid Monitoring System
Regulation Number: 21 CFR 862.1775
Regulation Name: Uric acid test system
Regulatory Class: I, Reserved
Product Code: PTC
Dated: April 4, 2017
Received: April 5, 2017

Dear Eliza Wang:

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,

Kellie B. Kelm -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160990

Device Name

Nova Max Uric Acid Monitoring System

Indications for Use *(Describe)*

The Nova Max Uric Acid Monitoring System consists of Nova Max Uric Acid Monitor, Nova Max Uric Acid Test Strips and Nova Max Uric Acid Control Solutions. The Nova Max Uric Acid Monitoring System is intended to be used for the quantitative measurement of Uric Acid in fresh capillary whole blood obtained from the fingertip of gout patients. It is intended for single-patient home use by prescription and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with gout as an aid to monitor the effectiveness of Uric Acid control. It is intended for use by patients undergoing treatment for gout or their caregivers on the order of a treating healthcare professional. This system should not be used to alter gout treatment by changing any medication schedule or dosage unless specifically instructed by a healthcare professional. This system should only be used with single-use, auto-disabling Lancing Devices. It should only be used with Nova Max Uric Acid Test Strips and Nova Max Uric Acid Control Solutions.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Owner:	Nova Biomedical Corporation
Registration Number:	1219029
Address:	200 Prospect St. Waltham, MA 02454
Phone:	781-647-3700 * 743
Fax Number:	781-891-4806
Contact Person:	Eliza Wang, RAC Regulatory Affairs Project Manager
Date Prepared:	April 10th, 2017
Proprietary Name:	Nova Max Uric Acid Monitoring System
Common or Usual Name:	Acid, uric, uricase (oxygen rate)
Classification Name:	Uric Acid Test System
Class Panel:	75
Regulation Number:	21 CFR 862.1775
Product Codes:	PTC
Classification:	I, reserved
Predicate Device:	The URCA Method on the Dimension® RxL Max™ Clinical Chemistry System (K043546)

Intended Use:

The Nova Max Uric Acid Monitoring System consists of Nova Max Uric Acid Monitor, Nova Max Uric Acid Test Strips and Nova Max Uric Acid Control Solutions. The Nova Max Uric Acid Monitoring System is intended to be used for the quantitative measurement of Uric Acid in fresh capillary whole blood obtained from the fingertip of gout patients. It is intended for single patient home use by prescription and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with gout as an aid to monitor the effectiveness of Uric Acid control. It is intended for use by patients undergoing treatment for gout or their caregivers on the order of a treating healthcare professional. This system should not be used to

alter gout treatment by changing any medication schedule or dosage unless specifically instructed by a healthcare professional. This system should only be used with single-use, auto disabling Lancing Devices. It should only be used with Nova Max Uric Acid Test Strips and Nova Max Uric Acid Control Solutions.

Device Description:

The Nova Max Uric Acid Monitoring System uses selective mediated enzymatic action (uricase biosensor) to generate current across the electrodes. The current generated is proportional to the concentration of Uric Acid in the whole blood sample. The device, which is amperometric, measures the Uric Acid concentration in the whole blood sample by measuring the amount of current that was generated and flows through the electrodes on the Test Strips.

The Nova Max Uric Acid Monitoring System is comprised of Nova Max Uric Acid Test Strips, a portable handheld Nova Max Uric Acid Monitor, and Nova Max Uric Acid Control Solutions.

Monitor Power Supply: The monitor uses single (3V) lithium, non-rechargeable battery. The battery life is approximately 1,000 tests.

No-Coding System: The user is not required to enter a Test Strip lot-specific Calibration Code into the monitor by pressing a button or by inserting a Code Key.

Uric Acid Control Solutions are aqueous assayed solutions, containing buffered Uric Acid, preservatives, FD & C dye, and viscosity additive. They contain no products of human origin. There are three levels of controls (level 1, 2, and 3).

Safety Lancets are provided as an accessory to the Nova Max Uric Acid Monitoring System. They are commercially available single-use, auto disabling sterilized Lancing Devices.

The Predicate Device: The URCA method on the Dimension® RxL Max™ Clinical System (K043546).

As demonstrated in Table 2-1 below, the Nova Max Uric Acid Monitoring System has the same intended use and scientific methodology as the URCA method on the Dimension RxL Max Clinical System.

Summary of the Technological Characteristics:

The Nova Max Uric Acid Monitoring System has similar fundamental scientific technology and intended use as the predicate URCA method on the Dimension® RxL Max™ Clinical Chemistry System (K043546). The Nova Max Uric Acid Monitoring System uses an enzymatic conversion of Uric Acid by uricase to quantitatively generate current on the electrode.

The current generated at the electrode is proportional to the Uric Acid concentration of the sample. By measuring the generated current, the concentration of Uric Acid in the sample is determined.

Comparison to the Predicate Device:

The Nova Max Uric Acid Monitoring System uses similar fundamental scientific technology and has the same intended use as the predicate device the URCA method on the Dimension® RxL Max™ Clinical Chemistry System (K043546).

Performance Studies:

Bench Testing:

- Linearity Study
- Day-to-Day Precision Study
- Within-run Precision Study
- Interference Study
- Cleaning and Disinfection Study
    - Pre and Post Cleaning and Disinfection Precision and Accuracy Study
    - Accelerated Bench Testing of Using Clorox Germicidal Disposable Wipes
- Hematocrit Range Validation Study
- Environmental Testing
    - Humidity and Temperature Validation Study
    - Oxygen / Altitude Validation Study
- Limit of Detection, Limit of Blank, Limit of Quantitation
- Short Sample Evaluation Study
- Stability Study
    - Shelf life Stability Study
    - Open Vial Validation Study
    - Transportation Stability Study

Human Factors Study:

A Human Factors study using 120 Layperson intended use subjects previously diagnosed with gout was conducted in the U.S. to evaluate the Nova Max Uric Acid Monitoring System with respect to ergonomics, ease-of-use, and instructions for use. This study was comprehensive and included feature/function tests and questionnaire items. Conclusions were based on the subjects' ability to demonstrate by action, their understanding of the components of the system, and their understanding of how to use the system (Successful performance of a Uric Acid whole blood capillary fingerstick test and a Uric Acid control solution test), comprehension of the contents of the instructions for use, as well as a user assessment questionnaire of the ease-of-use.

Performance of a Uric Acid test was performed using capillary whole blood from a fingerstick and Uric Acid Control Solution.

The Human Factors study demonstrates ease-of-use of the device as well as effectiveness of the Nova Max Uric Acid Monitoring System instructions for use.

Simplicity of Use Questionnaire:

Each layperson subject subsequently answered a 24-question Simplicity of Use Questionnaire covering general system questions, all labeling, and interpretation and what to do with their Uric Acid test results. The response to the questionnaire indicates that the participants were comfortable with the Nova Max Uric Acid Monitoring System, and lead to the conclusion that a typical layperson diagnosed with gout will find the monitor easy to operate, and the labeling easy to understand.

Normal Range Study:

A Normal Range Study was performed to determine reference uric acid levels in capillary whole blood obtained from the fingertip of adult subjects who do not take any medications known to affect Uric Acid levels in the blood, and who do not present with any conditions known to exhibit elevated or reduced levels of Uric Acid in the blood.

The central 95% reference interval for individuals is 3.6 - 7.7 mg/dL for Uric Acid in healthy males and 2.6 - 6.2 mg/dL for healthy females. These upper and lower reference limits show strong agreement with published ranges of serum Uric Acid levels in adult populations.

Clinical Study:

The layperson clinical study was conducted in two (2) phases.

The Phase 1 clinical study consisted of 120 layperson subjects previously diagnosed with gout. A total of three (3) different Nova Max Uric Acid Test Strips lots were used in the Phase 1 clinical study. Capillary fingertip whole blood Uric Acid measurements from the Nova Max Uric Acid Monitors were compared to the measurement of a venous (lithium heparin) whole blood sample from the same patient by the Siemens Dimension RxL Max Clinical Chemistry System (K043546).

The Phase 2 clinical study consisted of an additional 25 layperson subjects previously diagnosed with gout. The Phase 2 clinical study focused on obtaining elevated uric acid capillary specimens from lay person intended users. The measured Uric Acid range for the 25 additional intended use subjects was between 9.8 mg/dL and 17.5 mg/dL. Capillary whole blood fingertip Uric Acid results from the Nova Max Uric Acid Monitoring System were compared with venous plasma specimens measured on the URCA method on the Siemens Dimension RxL Max Clinical Chemistry System (predicate device, reference method).

Clinical study accuracy for both phases was assessed by using traditional Linear Regression analysis. Deming Regression Analysis was also performed. The Acceptance Criteria for the clinical study was as follows:

- A Linear Regression Correlation Coefficient (R^2) of 0.95 or greater.
- A Linear Regression Slope of 0.94 – 1.06.

Clinical Study Conclusion:

The results of the layperson clinical study confirmed that the Nova Max Uric Acid Monitoring System is safe and effective for the intended use populations (persons diagnosed with Gout) and the Nova Max Uric Acid Monitoring System is substantially equivalent to the predicate device.

Table 2-1: Comparison of Predicate and Proposed device

	Predicate: K043546	Proposed: This submission
Device Name	Dimension® RxL Max™ Clinical Chemistry System with StreamLAB® Analytical Workcell and Sample Transfer Module	Nova Max® Uric Acid Monitoring System
Intended Use	For the quantitative measurement of uric acid.	Same
Enzyme	Uricase	Uricase, Peroxidase
Operating Principle	Uric Acid + 2H2O + O2 $\xrightarrow{Uricase}$ Allantoin + H2O + CO2 (Allantoin absorbs at 293 nm)	Uric Acid + O_2 + 2H_2O $\xrightarrow{Uricase}$ Allantoin + CO_2 + H2O2 Ferrocyanide + H2O2 $\xrightarrow{POD(Peroxidase)}$ Ferricyanide + H2O Ferricyanide $\xrightarrow{+e}$ Ferrocyanide (on electrode)
Sample type	Serum, Plasma	Capillary Whole Blood obtained from the fingertip
Sample size	17 µL	1.2 µL
Measuring range	0-20.0 mg/dL	3 -18 mg/dL
Precision	Not available	Within run CV% < 10%
Quality Control	2 levels	3 levels
Handheld	No	Yes

	Predicate: K043546	Proposed: This submission
Device Name	Dimension® RxL Max™ Clinical Chemistry System with StreamLAB® Analytical Workcell and Sample Transfer Module	Nova Max® Uric Acid Monitoring System
Test Strip	No	Yes
Data storage	At least 100,800 QC tests	400 sample and Control Solution tests
Power source	UPS (Uninterruptable Power Source)	3V Li Button Battery Type 2450
Dimensions	159cm x 170cm x 81cm	91mm x 58mm x 23mm
Weight	366kg	75g

Conclusion:

Based on the intended use, bench tests, human factors study, and layperson clinical study, it is concluded that the Nova Max Uric Acid Monitoring System is substantially equivalent to the predicate device.