DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 11 2007

Nova Biomedical Corp.
c/o Dr. Paul W. MacDonald
Chief Quality Assurance and Regulatory
Affairs Officer
200 Prospect Street
Waltham, MA 02454-9141

Re: k070960
Trade/Device Name: Nova StatStrip Xpress Glucose Hospital Meter
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: Class II
Product Code: CGA
Dated: June 19, 2007
Received: June 20, 2007

Dear Dr. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k070960

Device Name: **Nova StatStrip Xpress Glucose Hospital Meter**

Indications For Use:

The Nova StatStrip Xpress Glucose Hospital Meter System is intended for *in vitro diagnostic use* by health care professionals and for Point-Of-Care usage for the quantitative measurement of glucose in capillary, venous, arterial, and neonate whole blood. It is indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control.

Nova StatStrip Glucose Test Strips are intended for use only with Nova StatStrip Glucose Hospital Meters for quantitative tests. The glucose meter is intended to quantitatively measure glucose (sugar) in whole blood. The Glucose Meter is calibrated to provide plasma equivalent results to laboratory methods. Nova StatStrip Glucose Test Strips are for testing outside the body (in vitro diagnostic use only).

Nova StatStrip Control Solutions is intended for use with Nova StatStrip Glucose Hospital Meters and Nova StatStrip Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Level 1, Level 2, and Level 3). These solutions will be offered for sale separately from the meter.

Nova StatStrip Glucose Linearity Kit solutions are used to check the linearity of Nova StatStrip Glucose Hospital Meter Systems. There are five levels of linearity solutions, (Level 1, Level 2, Level 3, Level 4, and Level 5).

Prescription Use _X_____ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 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) K070960