



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Paul W. MacDonald
Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454

NOV - 1 2006

Re: k061830
Trade/Device Name: Nova Stat Profile Critical Care Xpress (CCX 1+) System
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG, JIT, JJY
Dated: October 17, 2006
Received: October 18, 2006

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.

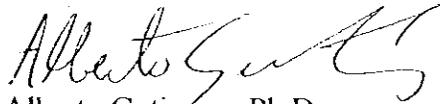
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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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) 276-0484. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Alberto Gutierrez, Ph.D.

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: K061830
Device Name: Nova Stat Profile Critical Care Xpress (CCX 1+) System
Indications for Use:

The Stat Profile Critical Care Xpress Analyzer is intended for *in vitro* diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of pH, PCO₂, PO₂, SO₂%, Hematocrit (Hct), total Hemoglobin (tHb), Oxyhemoglobin (O₂Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Reduced Hemoglobin (HHb), Oxygen content (O₂Ct), Oxygen capacity (O₂Cap), and total Bilirubin (tBil) in heparinized whole blood; Na⁺, K⁺, Cl⁻, Ca⁺⁺, Mg⁺⁺, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma. Total Bilirubin (tBil) was not evaluated on neonatal samples.

The intended use of the Nova Stat Profile Critical Care Xpress CO-Oximeter Calibrator Cartridge with Bilirubin and Deproteinizing Solution is for the quantitative determination of total hemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, deoxyhemoglobin and total bilirubin in human blood using the Stat Profile Critical Care Xpress CO-Oximeter Analyzer.

Nova Stat Profile Critical Care Xpress CO-Oximeter Controls and Autocartridge QC are intended for *in vitro* diagnostic use by healthcare professionals for monitoring the performance of Nova Biomedical Stat Profile Critical Care Xpress Analyzers.

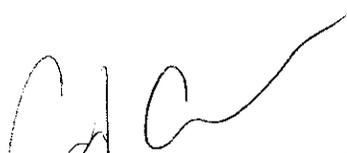
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)



Division Sign-Off

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Office of In Vitro Diagnostic Devices
Evaluation and Safety

(Updated February 3, 2005)

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