DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 12 1998

Paul W. MacDonald
Director of Quality Assurance/Regulatory Affairs
Nova Biomedical
200 Prospect Street
Waltham, Massachusetts 02254-9141

Re: K981426
STAT Profile Ultra F, G, H, I, J, K and L Analyzers
Regulatory Class: I & II
Product Code: GKF, GKR, CHL, CGZ, CDS, JIX, CEM, JFP, CGA, JGS, KHP, JJS
Dated: April 16, 1998
Received: April 16, 1998

Dear Mr. MacDonald:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

The motor chosen for Automator 2000 provides higher torque, is a preferable size for the Automator 2000 housing design, and requires less power.

Housing & Enclosure: The CF Automator (predicate device) has separately enclosed components that mount to the external fixator frame: drive units, controller, and battery pack. The components are connected by cables. By comparison, Automator 2000 has the control circuitry, drive components, and battery contained in a single housing. The compact and entirely self contained design of Automator 2000 simplifies the installation of the product. Furthermore, external cables are no longer vulnerable to damage or being inadvertently unplugged in the design of Automator 2000.

Automator 2000's machined aluminum housing is a robust design that comfortably accommodates the axial force and impact load requirements of the device. Additionally, the conductive aluminum housing has been designed to preclude radio frequency interference. By comparison, the CF Automator components are housed in delrin (a plastic composite), which is shaped by plastic injection molding.

Circuitry and Software/ Safety Features: Automator 2000's design has retained the CF Automator's redundant self diagnostic and circuitry controls to assure that the telescoping rod may move only the *amount* it is intended to move, and only *when* it is intended to move. Since each Automator 2000 device has its own control circuitry, the complexity built into the CF Automator circuitry for controlling multiple drive units has been removed. Since Automator 2000 is programmed using switches on the control board rather than through an IR communication link to a doctor's master computer, further communication circuitry has also been rendered unnecessary. Consequently, Automator 2000 has a more simplified circuit board and software package.

Programming the device has been simplified as well. The predicated device (CF Automator) allowed the physician to choose from 14 rate settings and 7 rhythm settings for the number of adjustment increments made by the device each day. Automator 2000 has 7 rate setting to chose from and the movement amount per increment is held constant at $1/360^{th}$ mm.

Regarding motor control, Automator 2000 and the CF Automator very similar software and circuitry safety features. Certain conditions that applied to the CF Model do not apply to Automator 2000 – for example, an unplugged drive unit or unplugged battery. Similarities between the two operating systems include the following: Both systems have been designed to use the *final* drive gear as an encoder to verify the position of the telescoping rod. Each system will error if the encoder does not verify that distraction is progressing within tolerable accuracy. Both systems check current on the motor circuit to verify the motor runs only when it is supposed to, and furthermore, check current during motor pulses to verify that current is not higher than expected. Both motor circuits have switches that remain open between motor pulses to prevent the motor from receiving current. Both systems use a watch-dog circuit to confirm software operation nearly continuously. Both systems have redundant audio and visual alarms. Furthermore, both units use the same design telescoping rod, which may be used to make manual lengthening adjustments at any time.