DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Novx Systems, Inc.
c/o Thomas Tsakeris, President,
Devices and Diagnosis Consulting Group
16809 Briardale Road
Rockville, MD 20853

OCT 31 2008

Re: k080057

Trade/Device Name: iMDx System
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Codes: DKZ, DLJ, DIF, LDJ, DJG, LCM
Dated: October 22, 2008
Received: October 23, 2008

Dear Mr. Tsakeris:

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

Indication for Use

510(k) Number: K080057

Device Name: iMDx System

Indication for Use:

The iMDx™ System is an in vitro diagnostic device consisting of iMDx™ Analyzer and iMDxPrep™ Assays. The system is an expandable, closed system. All assays are designed for use with automated iMDx™ Analyzer. The system has been designed to be used by practitioners in drug rehabilitation clinics, physician offices, and clinical laboratories.

The Amphetamines (Amphetamines and Methamphetamine), Oxycodone (Oxycodone), Phencyclidine (Phencyclidine) and Cannabinoids (Δ^9-THC-COOH) assays are enzyme immunoassays with cutoffs of 1000 ng/mL, 100ng/mL, 25 ng/mL and 50 ng/mL, respectively. These assays are intended for use in the qualitative and semi-quantitative analysis of Amphetamine, Oxycodone, Phencyclidine and Cannabinoids in human urine.

Semi-quantitative analysis is for the estimation of dilution for confirmation testing and to establish quality control procedures and assess quality control performance in general. Periodic calibration and use of control are required to maintain testing accuracy and assay performance.

All assays provide only a preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) analysis is performed. FOR USE BY TRAINED PERSONNEL ONLY. Only operators trained in the use of the iMDx™ System by NOVX personnel should perform these procedures.

Prescription Use ___×___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (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)

Carol C. Benson

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

510(k) K080057