



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOVX Systems Inc.
c/o Mr. Thomas Tsakeris
Devices & Diagnostics Consulting Group Inc.
16809 Briardale Road
Rockville, MD 20855

JUN - 1 2007

Re: k063699

Trade Name: iMDx™ System
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system.
Regulatory Class: Class II
Product Code: DJG, DMT, JXM, DJR, DIO, DKB, JJE and DIF

Dated: April 10, 2007
Received: April 11, 2007

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).

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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) 276-0490. 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): k063699

Device Name: iMDx System

Indications 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 Opiates (Morphine), Benzodiazepine (Oxazepam) and Cocaine Metabolite (Benzoylcegonine) Assays are an enzyme immunoassay with a 300ng/mL cutoff. These assays are intended for use in the qualitative and semi-quantitative analysis of Opiates, Benzodiazepine and Cocaine Metabolite in human urine. The Methadone Metabolite (EDDP) Assay is an enzyme immunoassay with a 100ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analysis of Methadone Metabolite in human urine. For point of care use semi-quantitative analysis is only for estimation of dilution for confirmation testing.

The Ethyl Alcohol Assay is an enzymatic assay intended for use in quantitative analysis of ethyl alcohol in human urine. Measurements contained are used in the diagnosis and treatment of alcohol intoxication and poisoning.

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 x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K063699