MAY 25 2005 EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K050594

1. Submitter's Identification:

Nano-Ditech Co.
11 Deer Park Dr., Suite 118
Monmouth Junction, NJ 08852
Tel: 732-438-8616
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Contact: Anand Akerkar, Ph.D.

Date Summary Prepared: March 7, 2005

2. Name of the Device:

Nano-Check™ DAT 5 Multi Drug Screening Test for Cannabinoids (THC), Opiates, (OPI), Cocaine (COC), Methamphetamine (mAMP) and Phencyclidine (PCP)

Also known as: The Nano-Check™ DAT 5M Test

Common or Usual Name:

Rapid, One-Step Qualitative Immuno-Chromatographic Assay for Multi Panel Drug of Abuse Test

3. Predicate Device Information:

1. ACON THC One Step Marijuana Test Strip, ACON Laboratories, Inc., San Diego, CA, K003557

2. ACON OPI One Step Opiates Test Strip, ACON Laboratories, Inc., San Diego, CA, K040274

3. ACON COC One Step Cocaine Test Strip, ACON Laboratories, Inc., San Diego, CA, K010841

4. ACON mAMP One Step Methamphetamine Test Strip, ACON Laboratories, Inc., San Diego, CA, K011672

5. ACON PCP One Step Phencyclidine Test Strip, ACON Laboratories, Inc., San Diego, CA, K011730

4. Device Description:

The Nano-Check™ DAT 5M test is a one step, type II, competitive immuochromatographic assay for the qualitative detection of Cannabinoid, Opiate, Benzoylecgonine, Methamphetamine and Phencyclidine compounds and their metabolites in human urine. The Nano-Check™ DAT 5M test device contains a membrane strip on which either antibodies against drug or drug conjugate to protein are immobilized at each specific test line. The colored indicator antibody or antigen coupled with Gold colloidal particles is place at the end of membrane.

The test is a single-use visually read cassette device in a plastic housing. It contains the test strip containing 5 test lines and 1 control line. Urine sample can be dropped onto sample well using plastic disposable dropper, which is provided. Drug positive urines will not show a colored band, while drug negative urine sample or urine sample containing drugs below cutoff level will generate red colored band.

The device is sealed in a pouch desiccant and provided with instructions for use and a disposable sample dropper.

Test Principle:

The Nano-Check™ DAT 5M test is a one step, type II, competitive immuochromatographic assay for the qualitative detection of Cannabinoid, Opiate, Benzoylecgonine, Methamphetamine and Phencyclidine compounds and their metabolites in human urine. The Nano-Check™ DAT 5M test device contains a membrane strip on which either antibodies against drug or drug conjugate to protein are immobilized at each specific test line. The colored indicator antibody or antigen coupled with Gold colloidal particles is place at the end of membrane.

When the test urine is applied on to the sample well of the device, the colored indicator particles move along with sample urine across membrane by the capillary action. If any of specified drugs in urine specimen, it competes with either colored indicator drug conjugate or drug antibodies for the limited amount antibodies or drug conjugates immobilized on the membrane. If equal or more than cut off concentration of drug or its metabolite is present in the sample urine,

the drug compounds will prevent the binding of drug conjugate to the target antibody. Thus positive drug urines will not show a colored band at the indicted drug test line on the membrane. Absence of colored band at a specific drug line indicated positive results, while the presence of colored band indicated a negative result for the specific drug. The control line is present in the test window for self-procedure validation control. This colored control band always appears at the control line position (CON) in the valid test results. Any test results is not valid if the control line does not appear in the test window.

5. Intended Use:

The Nano-Check™ DAT 5 Multi Drug Screening Test for Marijuana, Opiates, Cocaine, Methamphetamine and Phencyclidine is a rapid, self-controlled immunoassay for the qualitative detection of Cannabinoids (THC), Opiates (OPI), Benzoylecgonine (COC), Methamphetamine (mAMP) and Phencyclidine (PCP) compounds and their metabolites in human urine. The detection limits (cut-off concentrations) of this test are as follows: Cannabinoids at 50 ng/ml, Opiates at 2000 ng/ml, Cocaine at 300 ng/ml, Methamphetamine at 1000 ng/ml and Phencyclidine at 25 ng/ml. This assay is intended for Professional and Laboratory In-Vitro Use Only.

6. Comparison to Predicate Devices:

Overall performance and characteristics of the Nano-Check™ DAT 5M Test compared to the predicate devices (cited below), are summarized in the table below:

COMPARISON TABLE

Item	**Device**	**Predicates**				
		THC Marijuana test strip	OPI Opiate test strip	COC Cocaine test strip	mAMP methamphetamine test strip	PCP Phencyclidine test strip
Similarities						
Test Principle	Immunochromatographic, lateral-flow, competitive assay	Same				
Type of test	Qualitative	Same				
Assay time	10 min	Same				
Sample type	Human urine	Same				
Intended use	Professional use	Same				
Cutoff	THC:50ng/ml	Same				

concentration	OPI:2000 ng/ml COC:300 ng/ml mAMP:1000 ng/ml PCP: 25 ng/ml	
Differences		
# test /strip	Multiple (5 tests / strip)	Single (1 test/strip)
Sample application	Transfer urine specimen with disposable pipette	Immerse the test strip in the urine specimen

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following performance characteristics were addressed to support this submission.

a. Analytical Performance

- Precision/Reproducibility
- Traceability, stability, expected values
- Detection Limit
- Analytical Specificity
- Assay Cut-off

b. Comparison Studies to Predicates

- Method Comparison with Predicate Devices

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The submitted data for this premarket notification support a substantial equivalence decision for the Nano-Check™ DAT 5 Multi Drug Screening Test THC/OPI/COC/mAMP/PCP in comparison to the ACON One Step Single Test Strips, K003557, K040274, K010841, K011672, and K011730.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Nano-Ditech Co.
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd
Suite 200
Great Neck, NY 11021

MAY 25 2005

Re: k050594
Trade/Device Name: Nano- Check™ DAT 5 Multi Drug Screening Test for Cannabinoids (THC), Opiates (OPI), Cocaine (COC), Methamphetamine (mAMP) and Phencyclidine (PCP)
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ, DIO, DJC, DJG, LCM
Dated: March 7, 2005
Received: March 8, 2005

Dear Ms. Goldstein-Falk:

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) 276-0484. 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,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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: K050594

Device Name: **Nano-Check™ DAT 5 Multi Drug Screening Test for Cannabinoids (THC), Opiates (OPI), Cocaine (COC), Methamphetamine (mAMP) and Phencyclidine (PCP)**

Indications For Use:

The Nano-Check™ DAT 5 Multi Drug Screening Test for Marijuana, Opiates, Cocaine, Methamphetamine and Phencyclidine is a rapid, self-controlled immunoassay for the qualitative detection of Cannabinoids (THC), Opiates (OPI), Benzoylecgonine (COC), Methamphetamine (mAMP) and Phencyclidine (PCP) compounds and their metabolites in human urine. The detection limits (cut-off concentrations) of this test are as follows: Cannabinoids at 50 ng/ml, Opiates at 2000 ng/ml, Cocaine at 300 ng/ml, Methamphetamine at 1000 ng/ml and Phencyclidine at 25 ng/ml. This assay is intended for Professional and Laboratory In-Vitro Use Only.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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) K050594