K050975

MAR 2 2006

510(K) SUMMARY of Nano-Check™ AMI 3 IN 1 Test

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:_____.

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: Mr. Thomas Cekoric, Jr.
President/CEO

Date Summary Prepared: February 28, 2006

2. Name of the Device:

Nano-Check™ AMI 3 IN 1 Cardiac Marker Test cTnI, CK-MB and Myoglobin

Common or Usual Name:

Immuno Assay Method, Troponin Subunit, Chromatographic Separation, CPK ISO Enzymes

3. Predicate Device Information:

Spectral Cardiac STATus™ CK-MB-Myoglobin/Troponin I 3-in-1 test
K030057

Spectral Diagnostics Systems
135 The West Mall
Toronto, Ontario
Canada M9C 1C2

4. Device Description:

The Nano-Check ™ AMI 3 IN 1 Test is a one-step lateral flow immunochromatography assay for the qualitative determination of three cardiac markers simultaneously in serum and heparin plasma.

The test is a single-use, visually read, cassette device in a plastic housing. Membrane strip inside the plastic housing contains immobilized molecules at three test lines and one control line; CK-MB antibody, Myoglobin antibody, streptavidine and goat anti-mouse antibody. Dye pad at the end of the membrane strip contains biotinylated cTnI antibody and gold colloidal particles coupled with CK-MM, cTnI and Myoglobin antibodies. Cutoff level of each marker is 0.5 ng/ml, 5 ng/ml and 80 ng/ml for cTnI, CK-MB and Myoglobin respectively.

Device is sealed in pouch with desiccant and provided with instructions for use and disposable sample dropper.

Test Principle:

The Nano-Check ™ AMI 3 IN 1 Test is an immunochromatography assay for the qualitative determination of three biochemical markers (cTnI, CK-MB and Myoglobin) simultaneously in serum and heparin plasma. The membrane strip contains three test lines and one control line; immobilized monoclonal mouse antibody against CK-MB, monoclonal mouse antibody against Myoglobin, streptavidin for biotinylated cTnI antibody, and goat anti-mouse antibody for control line. A dye pad is placed at the end of the membrane containing biotinylated cTnI antibody and gold colloidal particles coupled with CK-MM, cTnI and Myoglobin antibodies. When a sample is applied into the sample well, the cardiac makers present in the sample bind to the specific antibodies coupled with gold particles. cTnI in a sample binds to both cTnI specific dye coupled antibody and biotinylated antibody. The immune complexes move along the nitrocellulose membrane through the test lines and bind to their corresponding capture antibodies immobilized on the test line. Unbound immune complexes pass through the test line and are captured by goat anti mouse antibody in the control line.

If the concentration of any of these three markers in the sample is above the cutoff level, red bands appear at the corresponding test lines and the control line. If the concentration of the markers in the sample is lower than the cutoff level, only the colored control line can be seen in the test window.

The control line is an internal control to ensure that an adequate volume of sample has been added. This colored control band must always appear at the control line position (Con) for valid test results. A test result is not valid if the colored control line does not appear in the test window.

5. Intended Use:

The Nano-Check ™AMI 3 IN 1 Test is a rapid immunoassay for the qualitative determination of Cardiac Troponin I (cTnI), Creatine Kinase MB (CK-MB), and Myoglobin in human serum and plasma specimens at cutoff concentrations of 0.5 ng/ml, 5.0 ng/ml, and 80 ng/ml, respectively, as an aid in the diagnosis of Acute Myocardial Infarction (AMI).

The Nano-Check™ AMI 3 IN 1 Test is a qualitative assay, which can not monitor the rise and fall of cTnI, CK-MB, and Myoglobin in single testing. Single testing is not recommended for AMI monitoring. Test results should be interpreted by the physician in conjunction with other laboratory test results and patient clinical findings.

6. Comparison to Predicate Devices:

Overall performance and characteristics of the Nano-Check™ AMI 3 IN 1 Test compared to the predicate devices (cited below), are summarized in the table below:

COMPARISON TABLE

Item	Device	Predicates
	Nano-Check™ AMI 3 IN 1, Cardiac Marker Test, cTnI, CK-MB, and Myoglobin	Spectral Cardiac STATus™ CK-MB-Myoglobin/Troponin I 3-in-1 test
Similarities		
Analyte	cTnI, CK-MB, and Myoglobin	Same
Test Principle	Lateral-flow, immunochromatographic Test	Same
Type of test	Qualitative	Same
Assay time	15 minutes	Same
Intended use	Professional use	Same
Cutoff concentration	cTnI: 0.5 ng/ml CK-MB: 5 ng/ml Myoglobin: 80 ng/ml	Same
Differences		
# test /strip	Multiple (3 tests / strip)	Multiple (3 tests / 2 strips)
Capture molecule in test line	cTnI: Streptavidin Myo: Monoclonal mouse anti-Myo antibody	cTnI: Streptavidin Myo: Polyclonal rabbit anti-myo antibodies

	CKMB: Monoclonal mouse anti-CKMB antibody	CKMB: Polyclonal goat anti-CKMM antibodies
Conjugate molecule	cTnI: Dye coupled with monoclonal mouse anti-cTnI antibody and biotinylated monoclonal mouse anti-cTnI antibody Myo: Dye coupled with monoclonal mouse anti-Myo antibody CKMB: Dye coupled with monoclonal mouse anti-CKMM	cTnI: Dye coupled with monoclonal anti-cTnI antibody and biotinylated polyclonal rabbit anti-cTnI antibodies Myo: Dye coupled with anti-Myo antibody CKMB: Dye coupled with monoclonal mouse anti-CKMB
Sample type	Serum or Plasma (heparin as anticoagulant)	Whole blood, serum or plasma (heparin as anticoagulant)
Sample application volume	200~250μl in one sample well	Total of 300 μl in two sample wells
Storage temperature	2-30°C	15-30°C

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 Predicate

- Method Comparison with Predicate Device

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The submitted data for this subject premarket notification supports a substantial equivalence decision for the Nano-Check™ AMI 3 IN 1 Cardiac Marker Test cTnI, CK-MB and Myoglobin, by comparison with the predicate device the Spectral Cardiac STATus™ CK-MB-Myoglobin/Troponin I 3-in-1 test, K030057.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 2006

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

Re: k050975
Trade/Device Name: Nano-Check™ AMI 3 in 1 Cardiac Marker Test cTnI, CK-MB And Myoglobin
Regulation Number: 21 CFR§862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI, JHT, DDR
Dated: February 21, 2006
Received: February 22, 2006

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,

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

510(k) Number (if known): K050975

Device Name: Nano-Check™ AMI 3 IN 1 Cardiac Marker Test cTnI, CK-MB and Myoglobin

Indications For Use:

The Nano-Check ™AMI 3 IN 1 Test is a rapid immunoassay for the qualitative determination of Cardiac Troponin I (cTnI), Creatine Kinase MB (CK-MB), and Myoglobin in human serum and plasma specimens at cutoff concentrations of 0.5 ng/ml, 5.0 ng/ml, and 80 ng/ml, respectively, as an aid in the diagnosis of Acute Myocardial Infarction (AMI).

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Prescription Use __X__ **OR** **Over-The Counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K050975

Concurrence of CDRH, Office of Device Evaluation (ODE)