



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 2 2004

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Michael Friedman, MBA, Ph.D.  
N-Dia, Inc.  
30 E. 20<sup>th</sup> Street, Ste. 501  
New York, NY 10003

Re: k030849  
Trade/Device Name: AmniSure™ ROM (Rupture of [fetal] Membranes) Test  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: Class I  
Product Code: JJX; NQM  
Dated: October 19, 2003  
Received: November 4, 2003

Dear Dr. Friedman:

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.

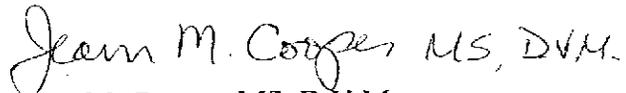
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (301) 594-3084. 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/dsma/dsmamain.html>.

Sincerely yours,



Jean M. Cooper, MS, 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

510(k) Number (if known): K030849/S001

Device Name: AmniSure™ ROM (Rupture Of [fetal] Membranes) Test

Indications for Use:

The AmniSure™ ROM (Rupture Of [fetal] Membranes) Test is a rapid, non-instrumented, qualitative immunochromatographic test for the *in vitro* detection of amniotic fluid in vaginal secretions of pregnant women. AmniSure detects PAMG-1 protein marker of the amniotic fluid in vaginal secretions. The test is for use by health care professionals to aid in the detection of ROM in pregnant women at > 34 weeks gestation when patients report signs, symptoms or complaints suggestive of ROM.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  or Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) k030849