DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUL 24 2009

Nanosphere, Inc.
c/o Dr. Gregory W. Shipp
Vice President, Medical and Regulatory Affairs and Quality Assurance
4088 Commercial Avenue
Northbrook, IL 60062

Re: k083294
Trade/Device Name: Verigene® CFTR and Verigene® CFTR PolyT Nucleic Acid Test
Regulation Number: 21 CFR 866.5900
Regulation name: CFTR (cystic fibrosis transmembrane conductance regulator) gene mutation detection system
Regulatory Class: Class II
Product Code: NUA
Dated: June 19, 2009
Received: June 22, 2009

Dear Mr. Shipp,

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office or In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Leena Philip

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for use

510(k) Number (if known): k083294

Device Names: Verigene® *CFTR* and Verigene® *CFTR* PolyT Nucleic Acid Tests

Indications for Use:
The Verigene®*CFTR* and Verigene®*CFTR* PolyT Nucleic Acid Tests are qualitative *in vitro* diagnostic devices used to genotype a panel of mutations and variants in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene in genomic DNA isolated from human peripheral whole blood specimens. The panel includes mutations and variants recommended by the 2004 American College of Medical Genetics (ACMG) and the 2005 American College of Obstetricians and Gynecologists (ACOG). The Verigene®*CFTR* Nucleic Acid Test provides information intended to be used for carrier testing in adults of reproductive age and in confirmatory diagnostic testing of newborns and children.

These tests are not indicated for use in fetal diagnostic or pre-implantation testing and not indicated for stand-alone diagnostic purposes. The results should be used in conjunction with other available laboratory and clinical information. Both tests are intended to be used on the Verigene System.

Prescription Use ___X___ and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Teena Philip (For Marcia Chan)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k083294