DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. E. Joseph McMullen
Senior Regulatory Affairs Specialist
Gen-Probe, Inc.
10210 Genetic Center Drive
San Diego, CA 92121-4362

MAY 21 2001

Re: 510(k) Number: K003395
Trade/Device Name: Gen-Probe® Aptima™ Combo 2 Assay
Regulation Number: 866.3390
Regulatory Class: II
Product Code: LSL
Dated: October 31, 2000
Received: November 1, 2000

Dear Mr. McMullen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.B. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):_____

Device Name: GEN-PROBE APTIMA Combo 2 Assay

Indications for Use:
The GEN-PROBE APTIMA Combo 2 Assay is for use in clinical diagnostic laboratories. This assay is a target-amplified nucleic acid probe test used for the *in vitro* diagnostic qualitative detection of rRNA from *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in endocervical and male urethral swab specimens and urines from symptomatic and asymptomatic males and females.

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003395

PRESCRIPTION USE X