5.0 510(k) SUMMARY

K062440 NOV - 7 2006

GEN-PROBE® APTIMA® Assay for *Neisseria gonorrhoeae*

General Information

Submitted By:	Company Contact:
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Trade Name: GEN-PROBE® APTIMA® Assay for *Neisseria gonorrhoeae*

Common or Usual Name: rRNA target-amplified nucleic acid probe test for the *in vitro* diagnostic detection of *Neisseria gonorrhoeae*

Classification Name: DNA Reagents, *Neisseria*

Classification Code:

Medical Specialty: Microbiology

Product Code: LSL

Registration Number: CFR 866.3390

Device Class: 2

Description: Reagents used to identify Neisseria spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Neisseria, such as epidemic cerebrospinal meningitis, meningococcal disease, and gonorrhea, and also provides epidemiological information on diseases caused by these microorganisms.

Substantially Equivalent Devices:

GEN-PROBE® APTIMA® Assay for *Neisseria gonorrhoeae*

Device Description

Clearance of this premarket notification extends the clinical performance claims of the commercially available GEN-PROBE APTIMA Assay for *Neisseria gonorrhoeae* to include PreservCyt liquid Pap specimens (collected and processed by the Cytyc ThinPrep 2000 Processor) as acceptable testing specimens. The ancillary kit formulated for this specific application is the commercially available GEN-PROBE APTIMA Specimen Transfer Kit. The components of the APTIMA Specimen Transfer Kit include: (1) a transport tube containing transport media with a penetrable cap and (2) specific instructions for use regarding decontamination and specimen processing procedures. The APTIMA Specimen Transfer Kit may only be used in conjunction with GEN-PROBE APTIMA Assays for the detection of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae.*

Intended Use

APTIMA Assay for *Neisseria gonorrhoeae* package insert:
The APTIMA® Assay for *Neisseria gonorrhoeae* is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection of ribosomal RNA (rRNA) from *Neisseria gonorrhoeae* (GC) to aid in the diagnosis of gonococcal urogenital disease. The assay may be used to test the following specimens from symptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens; and patient-collected female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected endocervical and vaginal swab specimens; and patient-collected vaginal swab specimens[1] and female and male urine specimens. The assay is also intended for use with the testing of gynecological specimens collected in the PreservCyt Solution and processed with the Cytyc ThinPrep 2000 System.

[1] Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The vaginal swab specimen collection kit is not for home use.

Ancillary Kit package insert:

The GEN-PROBE APTIMA Specimen Transfer Kit is only for use with GEN-PROBE APTIMA Assays for the detection of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*. The GEN-PROBE APTIMA Specimen Transfer Kit allows for APTIMA Assay testing of gynecological specimens collected and processed by the Cytyc ThinPrep 2000 Processor according to the instructions provided.

APTIMA Assay for *Neisseria gonorrhoeae*

A complete description of the APTIMA Assay for *Neisseria gonorrhoeae* is provided in the commercialized package insert.

Summary of Non-Clinical (Analytical Laboratory) Performance Data

Limit of Detection (Analytical Sensitivity)

N. gonorrhoeae analytical sensitivity (limit of detection) was determined by directly comparing dilutions of 51 different clinical isolates in culture and in the APTIMA GC Assay. The analytical sensitivity claim for the assay is 50 cells/assay (362 cells/swab, 250 cells/mL urine, 487.5 cells/mL PreservCyt Solution liquid Pap).

Analytical Specificity

A total of 154 culture isolates were evaluated using the APTIMA GC Assay. These isolates included 86 organisms that may be isolated from the urogenital tract and 68 additional organisms that represent a phylogenetic cross-section of organisms. The tested organisms included bacteria, fungi, yeast, parasites and viruses. All organisms except *C. psittaci, C. pneumoniae, U. urealyticum* and the viruses were tested at 1.0×10^6 cells/assay in Kova-trol/urine transport media and 60 organisms were tested in swab transport media. *C. psittaci* VR601 was tested at 8×10^4 cells/assay and *C. psittaci* VR125 was tested at 1×10^5 cells/assay. *C. pneumoniae* was tested at 4×10^3 cells/assay and *U. urealyticum* was tested at 6.7×10^6 cells/assay. The viruses were tested as follows: (a) herpes simplex virus I: 2.5×10^4 $TCID_{50}$/assay, (b) herpes simplex virus II: 6.0×10^4 $TCID_{50}$/assay, (c) human papillomavirus 16: 2.9×10^6 DNA copies/assay and (d) cytomegalovirus: 4.8×10^5 cells/assay. The list of organisms tested is shown in Table 1.

Table 1: APTIMA GC Assay Analytical Specificity

ORGANISM	ORGANISM	ORGANISM
Achromobacter xerosis	*Escherichia coli*	*Neisseria mucosa* (3)
Acinetobacter calcoaceticus	*Flavobacterium meningosepticum*	*Neisseria sicca* (3)
Acinetobacter Iwoffi	*Fusobacterium nucleatum*	*Neisseria subflava* (14)
Actinomyces israelii	*Gardnerella vaginalis*	*Neisseria perflava*
Actinomyces pyogenes	*Gemella haemolysans*	*Neisseria polysaccharea*
Aerococcus viridans	*Haemophilus ducreyi*	*Paracoccus denitrificans*
Aeromonas hydrophila	*Haemophilus influenzae*	*Peptostreptococcus anaerobius*
Agrobacterium radiobacter	Herpes simplex virus I	*Peptostreptococcus productus*
Alcaligenes faecalis	Herpes simplex virus II	*Plesiomonas shigelloides*
Bacillus subtilis	Human papilloma virus 16	*Propionibacterium acnes*
Bacteriodes fragilis	*Kingella dentrificans*	*Proteus mirabilis*
Bacteriodes ureolyticus	*Kingella kingae*	*Proteus vulgaris*
Bifidobacterium adolescentis	*Klebsiella oxytoca*	*Providencia stuartii*
Bifidobacterium brevi	*Klebsiella pneumoniae*	*Pseudomonas aeruginosa*
Branhamella catarrhalis	*Lactobacillus acidophilus*	*Pseudomonas fluorescens*
Brevibacterium linens	*Lactobacillus brevis*	*Pseudomonas putida*
Campylobacter jejuni	*Lactobacillus jensonii*	*Rahnella aquatilis*
Candida albicans	*Lactobacillus lactis*	*Rhodospirillum rubrum*
Candida glabrata	*Legionella pneumophila* (2)	*Saccharomyces cerevisiae*
Candida parapsilosis	*Leuconostoc paramensenteroides*	*Salmonella minnesota*
Candida tropicalis	*Listeria monocytogenes*	*Salmonella typhimurium*
Chlamydia pneumoniae	*Micrococcus luteus*	*Serratia marcescens*
Chlamydia psittaci (2)	*Moraxella lacunata*	*Staphylococcus saprophyticus*
Chromobacterium violaceum	*Moraxella osloensis*	*Staphylococcus aureus*
Citrobacter freundii	*Morganella morganii*	*Staphylococcus epidermidis*
Clostridium perfringens	*Mycobacterium smegmatis*	*Streptococcus agalactiae*
Corynebacterium genitalium	*Mycoplasma genitalium*	*Streptococcus bovis*
Corynebacterium xerosis	*Mycoplasma hominis*	*Streptococcus mitis*
Cryptococcus neoformans	*N. meningitidis* Serogroup A	*Streptococcus mutans*
Cytomegalovirus	*N. meningitidis* Serogroup B	*Streptococcus pneumoniae*
Deinococcus radiodurans	*N. meningitidis* Serogroup C (4)	*Streptococcus pyogenes*
Derxia gummosa	*N. meningitidis* Serogroup D	*Streptococcus salivarius*
Eikenella corrodens	*N. meningitidis* Serogroup Y	*Streptococcus sanguis*
Enterobacter aerogenes	*N. meningitidis* Serogroup W135	*Streptomyces griseinus*
Enterobacter cloacae	*Neisseria cinerea* (4)	*Trichomonas vaginalis*
Entercoccus avium	*Neisseria dentrificans*	*Ureaplasma urealyticum*
Entercoccus faecalis	*Neisseria elongata* (3)	*Vibrio parahaemolyticus*
Entercoccus faecium	*Neisseria flava*	*Yersinia enterocolitica*
Erwinia herbicola	*Neisseria flavescens* (2)	
Erysipelothrix rhusiopathiae	*Neisseria lactamica* (9)	

(n) = Number of strains tested
All organisms tested produced a negative result in the APTIMA GC Assay.

Interference Studies

The following interfering substances were individually spiked into swab, PreservCyt liquid Pap, and/or urine specimens: 10% blood, contraceptive jelly, spermicide, moisturizer, hemorrhoidal anesthetic, body oil, powder, anti-fungal cream, vaginal lubricants, feminine spray and leukocytes ($1x10^6$ cells/mL). The following interfering substances were individually spiked into urine specimens: 30% blood, urine analytes, protein, glucose, ketones, bilirubin,
nitrate, urobilinogen, pH 4 (acidic), pH 9 (alkaline), leukocytes ($1x10^6$ cells/mL), cellular debris, vitamins, minerals, acetaminophen, aspirin and ibuprofen. All were tested for potential assay interference in the absence and presence of GC at the estimated rRNA equivalent of 50 GC cells/assay (250 fg/assay). The rRNA equivalents were calculated based on the genome size and estimated DNA:RNA ratio/cell of each organism. No interference was observed with any of the tested substances. No inhibitors of amplification were observed in the APTIMA GC Assay.

Recovery

Escherichia coli, *Gardnerella vaginalis*, *Lactobacillus acidophilus*, *Bacteroides ureolyticus* and *Staphylococcus epidermidis* (1 x 10^8 cells/assay) were added to samples containing the rRNA equivalent of approximately 50 *N. gonorrhoeae* cells (250 fg). These additions did not interfere with the amplification and detection of *N. gonorrhoeae* rRNA using the APTIMA GC Assay.

Liquid Pap Specimen Stability Studies

Data to support the recommended shipping and storage conditions for PreservCyt Solution liquid Pap samples were generated with negative processed and unprocessed liquid Pap samples. For the unprocessed samples, four pools of PreservCyt Solution samples were tested after being stored in the Cytyc PreservCyt Solution vial. Each specimen pool was spiked with 50-100 CFU GC/assay, held at 2°C, 10°C, and 30°C, then tested at baseline and on days 5, 7, 8, 14, 18, 21, 25 and 36. All of the spiked samples were positive for GC at all times and temperatures. For the processed samples, four pools of PreservCyt Solution samples were used to determine processed specimen stability at 2°C to 30°C. Each negative sample pool was spiked with 50-100 IFU GC/assay, then tested at baseline. Prior to processing, the PreservCyt Solution samples were stored at 30°C for seven (7) days to simulate the time lapse between sample collection, Pap processing and shipment to a microbiology testing lab. After seven days at 30°C, 1 mL aliquots of each pool were transferred to an APTIMA Specimen Transfer Tube and tested at baseline before being placed at 2°C, 10°C, and 30°C. The processed samples were then tested for 17 days stored at 30°C and 36 days stored at 2°C to 10°C. All of the spiked samples were positive for GC at all times and temperatures. Data to support longer storage conditions were generated from four pools of negative processed PreservCyt Solution samples tested at below freezing temperatures. Each pool was spiked with 50-100 IFU CT/assay, then tested at baseline. Each pool was first placed at 30°C for 14 days and then stored at -20°C or -70°C over the course of 106 days. All of the spiked samples were positive for GC at all times and temperatures.

Precision

PreservCyt specimen within-laboratory precision with the APTIMA GC Assay was determined by spiking PreservCyt vials with 20 GC CFU per vial (0.1 CFU per reaction) and 100 GC CFU per vial (0.5 CFU per reaction). Vials containing 10,000 GC CFU per vial (50 CFU per reaction) and unspiked PreservCyt vials were tested as positive and negative controls. Ten vials spiked at each CFU level and ten unspiked vials were divided between two operators. The operators vortexed the vials and then transferred 14 aliquots (1.0 mL each) per vial into 14 APTIMA Transfer Tubes as per the APTIMA Specimen Transfer Kit package insert. The operators were blinded to the samples' titers. Each of the resulting Pap-STM samples was tested once in the APTIMA GC Assay. A total of five runs were performed over a five-day period for 140 results at the 0.1, 0.5, and 50 CFU level. There were 136 valid results and 4 invalid results for the negative control panel. The invalid results were due to a misplacement of a TTU in the Leader HC+. The results are summarized in Table 2.

Table 2: APTIMA GC Assay Within-laboratory Precision Data for PreservCyt Using a 4-Member Precision Panel Containing 0 to 500 CFU/mL GC Cells.

Panel Member	CFU/mL PreservCyt	CFU/rxn	n	Agreed	% Agrmt.	Mean RLU (x1000)	Within-Operator		Between-Day		Between-Operator		Total	
							SD (x1000)	CV (%)	SD (x1000)	CV (%)	SD (x1000)	CV (%)	SD (x1000)	CV (%)
A	1	0.1	140	39	27.9	313.7	758.3	241.7	132.5	42.2	0.0	0.0	769.8	245.4
B	5	0.5	140	113	80.7	1211.1	1031.3	85.2	169.8	14.0	150.4	12.4	1056.0	87.2
C	500	50	140	140	100	5636.8	220.7	3.9	135.7	2.4	0.0	0.0	259.1	4.6
D	0	0	136*	136	100	1.2	0.5	N/A	0	N/A	0.3	N/A	0.6	N/A

* There were four invalid results due to a misplaced TTU in the Leader HC+.

Note: Variability from some factors may be numerically negative, which can occur if the variability due to those factors is small. When this occurs, the variability as measured with SD and %CV is set to zero (13). N/A = Not applicable for negative panel members. Operator = Run. Samples with discordant results were included in the signal variability analysis.

Summary of Clinical Performance Data

A prospective multi-center clinical study was conducted to evaluate the use of the PreservCyt transport medium (a component of the ThinPrep 2000 System) as an alternative medium for gynecological specimens for the detection of *N. gonorrhoeae* by the APTIMA GC Assay. One thousand six hundred forty-six (1,646) symptomatic and asymptomatic female subjects attending OB/GYN, family planning, public health, women's, and STD clinics were evaluated in the clinical study. Of the 1,646 evaluable subjects, 1,287 were asymptomatic subjects and 359 were symptomatic subjects (Table 3). Subjects were enrolled from sites with GC prevalence that ranged from 0.0% to 5.0%. Two specimens were collected from each eligible subject: one PreservCyt liquid Pap specimen and one endocervical swab specimen. PreservCyt liquid Pap specimens were collected with the spatula/cyto-brush or a broom-like brush cervical sampling device. The distribution of cervical sampling devices is summarized in Table 4 by specimen collection site and overall. PreservCyt liquid Pap specimens were processed in accordance with the ThinPrep 2000 Processor Operator's Manual and APTIMA Specimen Transfer Kit package insert. After processing the PreservCyt liquid Pap specimen with the ThinPrep 2000 Processor, the specimen was transferred into the APTIMA Specimen Transfer Kit for testing with the APTIMA GC Assay. Sensitivity and specificity of the APTIMA GC Assay in PreservCyt liquid Pap specimens were calculated by comparing results to the patient infected status. The algorithm included APTIMA Combo 2 Assay and APTIMA GC Assay results in endocervical swab specimens. Both reference NAATs were required to be positive to establish an infected patient status. At least one reference NAAT was required to be negative to establish a non-infected patient status. If an equivocal result was obtained from any one of the reference NAATs, the patient infected status was categorized as inconclusive; these specimens were not included in the sensitivity and specificity calculations. Table 4 shows the sensitivities and specificities of the APTIMA GC Assay by symptom status and overall. Overall sensitivity was 92.3% (12/13). In symptomatic and asymptomatic subjects, sensitivities were 100% (7/7) and 83.3% (5/6), respectively. Overall specificity was 99.8% (1630/1633). In symptomatic and asymptomatic subjects, specificities were 99.4% (350/352) and 99.9% (1280/1281), respectively. Table 5 shows the sensitivities and specificities of the APTIMA GC Assay by specimen collection site and overall. Sensitivities ranged from 80.0% to 100%. Specificities ranged from 99.0% to 100%.

Table 3: Distribution of Cervical Sampling Device Used for PreservCyt Liquid Pap Specimens

Cervical Sampling Device Used	Clinical Collection Site						Total
	1	2	3	4	5	6	
Spatula/Cytobrush	0	124	475	287	57	364	1307
Broom-Type Device	100	0	0	0	240	0	340

Table 4: Performance of the APTIMA GC Assay in PreservCyt Liquid Pap Specimens by Symptom Status

	APTIMA GC PreservCyt Result	+/+	+/-	-/+	-/-	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)
Symptomatic	Positive	7	0	0	2	100 (7/7) (59.0 – 100)	99.4 (350/352) (98.0 – 99.9)
	Negative	0	0	0	350		
	Total	7	0	0	352		
Asymptomatic	Positive	5	0	0	1	83.3 (5/6) (35.9 – 99.6)	99.9 (1280/1281) (99.6 – 100)
	Negative	1	0	5	1275		
	Total	6	0	5	1276		
All	Positive	12	0	0	3	92.3 (12/13) (64.0 – 99.8)	99.8 (1630/1633) (99.5 – 100)
	Negative	1	0	5	1625		
	Total	13	0	5	1628		

+/+ = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

+/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Negative endocervical swab specimen result in the APTIMA GC Assay

-/+ = Negative endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

-/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

Table 5: Performance of the APTIMA GC Assay in PreservCyt Processed Liquid Pap Specimens by Collection Site

Site	APTIMA GC PreservCyt Result	+/+	+/-	-/+	-/-	Prev (%)	Sensitivity (%) (95% C.I.)	Specificity (%) (95% C.I.)	PPV(%)	NPV(%)
1	Positive	5	0	0	0	5.0	100 (5/5) (47.8 – 100)	100 (95/95) (96.2 – 100)	100	100
	Negative	0	0	0	95					
	Total	5	0	0	95					
2	Positive	1	0	0	0	0.8	100 (1/1) (2.5 – 100)	100 (123/123) (97.0 – 100)	100	100
	Negative	0	0	0	123					
	Total	1	0	0	123					
3	Positive	4	0	0	0	1.1	80.0 (4/5) (28.4 – 99.5)	100 (470/470) (99.2 – 100)	100	99.8
	Negative	1	0	0	470					
	Total	5	0	0	470					
4	Positive	1	0	0	3	0.3	100 (1/1) (2.5 – 100)	99.0 (283/286) (97.0 – 99.8)	25.0	100
	Negative	0	0	3	280					
	Total	1	0	3	283					
5	Positive	0	0	0	0	0.0	N/A	100 (297/297) (98.8 – 100)	N/A	100
	Negative	0	0	0	297					
	Total	0	0	0	297					
6	Positive	1	0	0	0	0.3	100 (1/1) (2.5 – 100)	100 (362/362) (99.0 – 100)	100	100
	Negative	0	0	2	360					
	Total	1	0	2	360					
ALL	Positive	12	0	0	3	0.8	92.3 (12/13) (64.0 – 99.8)	99.8 (1630/1633) (99.5 – 100)	80.0	99.9
	Negative	1	0	5	1625					
	Total	13	0	5	1628					

N/A = not applicable

+/+ = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

+/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Negative endocervical swab specimen result in the APTIMA GC Assay

-/+ = Negative endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

-/- = Positive endocervical swab specimen result in the APTIMA COMBO 2 Assay/Positive endocervical swab specimen result in the APTIMA GC Assay

Table 6: PreservCyt Liquid Pap Specimen Analysis for Patient Infected Status

Patient Infected Status	Endocervical Swab		Symptom Status	
	APTIMA COMBO 2 Assay	APTIMA GC Assay	Symptomatic	Asymptomatic
Inconclusive	E	P	0	1
Infected	P	P	7	6
Non-Infected	N	N	352	1276
Non-Infected	N	P	0	5
Total			359	1288

Prevalence

The prevalence of GC in patient populations depends on risk factors such as age, gender, the presence of symptoms, the type of clinic, and the test method. A summary of the prevalence of GC in North America, for PreservCyt liquid Pap specimens on the APTIMA GC Assay is shown in Table 7

Table 7: Prevalence of *N. gonorrhoeae* by Clinical Site and Overall as Determined by APTIMA GC Assay Results Using PreservCyt Liquid Pap Specimens

Site	% (#positive/#tested)	
1	5.0	(5/100)
2	0.8	(1/124)
3	0.8	(4/475)
4	1.4	(4/287)
5	0.0	(0/297)
6	0.5	(2/364)
All	1.0	(16/1647)

Conclusions from Non-Clinical and Clinical Data

The non-clinical and clinical study results support the use of PreservCyt liquid Pap specimens collected and processed by the Cytyc ThinPrep 2000 Processor in the currently marketed GEN-PROBE APTIMA Assay for *Neisseria gonorrhoeae*. The currently marketed GEN-PROBE APTIMA Specimen Transfer Kit provides necessary materials and instructions to allow for the testing of PreservCyt liquid Pap specimens in the APTIMA GC Assay.

The results of the clinical study demonstrate reasonable evidence that when the APTIMA GC Assay and the APTIMA Specimen Transfer Kit are labeled as proposed, the APTIMA GC Assay continues to be safe and effective for its stated intended use.

Contraindications and Cautions

There are no contraindications or cautions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 7 2006

Mr. E. Joseph McMullen
Associate Director, Regulatory Affairs
Gen-Probe Incorporated
10210 Genetic Center Drive
San Diego, CA 92121

Re: k062440
Trade/Device Name: GEN-PROBE® APTIMA® Assay for *Neisseria gonorrhoeae*
Regulation Number: 21 CFR 866.3390
Regulation Name: *Neisseria* spp. direct serological test reagents
Regulatory Class: Class II
Product Code: LSL
Dated: August 18, 2006
Received: August 21, 2006

Dear Mr. McMullen:

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)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

GEN-PROBE INCORPORATED
APTIMA Assay® for *Neisseria gonorrhoeae*

INDICATIONS FOR USE STATEMENT

510(k) Number:
(if known)

K062440

Device Name: GEN-PROBE APTIMA Assay® for *Neisseria gonorrhoeae*
Indications for Use:
The APTIMA® Assay for *Neisseria gonorrhoeae* is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection of ribosomal RNA (rRNA) from *Neisseria gonorrhoeae* (GC) to aid in the diagnosis of gonococcal urogenital disease. The assay may be used to test the following specimens from symptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected endocervical and vaginal swab specimens; and patient-collected vaginal swab specimens[1] and female and male urine specimens. The assay is also intended for use with the testing of gynecological specimens, from both symptomatic and asymptomatic patients, collected in the PreservCyt Solution and processed with the Cytyc ThinPrep 2000 System.

[1] Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The vaginal swab specimen collection kit is not for home use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) OR Over-the-Counter Use_____ (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062440