



HiFi[®] DNA



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August 13, 2007

Division of Dockets Management
Office of Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

Docket No. 2007P-0210

513(f) K063649 reclassification

Via Fed Ex delivery 8604 0044 1499

Dear Sir/Madam:

Thank you for your letter dated May 22, 2007 and publication of the petition on the dockets.

The official filing date of this reclassification petition under 513(f) is March 7, 2007. The file was mailed to Document Mail Room (HFZ-215), Center for Devices and Radiological Health (CDRH), Food and Drug Administration via Federal Express overnight delivery, as indicated on the covering letter of the petition. According to 21 CFR § 860.134 (b) (6) which governs review of 513(f) petitions, no more than 210 days after the date the petition was filed, the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. Hence, the undersigned respectfully requests that the FDA honors the time schedule set by the Code of Federal Regulations to notify the petitioner by order in the form of a letter the decision of the Commissioner by October 5, 2007.

For the public record, the petitioner is enclosing copy of a recent publication entitled "Routine human papillomavirus genotyping by DNA sequencing in community hospital laboratories" by Lee et al., in the journal of *Infectious Agents and Cancer*, based on the manuscript which forms reference 13 of this petition. The first draft of the manuscript for this publication was sent to the Dr. Steven I. Gutman, director of the Office of In Vitro Diagnostic Device Evaluation and Safety on October 30, 2006 in an attempt to seek his direction and advice to guide this application to no avail. No new information is being introduced.

Sincerely,

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Encl. "Routine human papillomavirus genotyping by DNA sequencing in community hospital laboratories" by Lee et al.

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