DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Sin Hang Lee, M.D.
President
HiFi DNA Tech, LLC
160 Hawley Lane
Trumbull, CT 06611

JAN - 9 2007

Re: k063649
Trade Name: HPV DNA Nest PCR Test™
Regulatory Class: III
Classification Regulation: Not applicable
Product Code: MAQ
Dated: December 7, 2006
Received: December 8, 2006

Dear Dr. Lee:

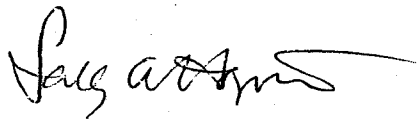
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We have determined that your device is an *in vitro* nucleic acid assay, using the nested polymerase chain reaction (PCR) technology, with target DNA amplification in PCR tubes or in microplate wells for the qualitative detection of Human Papillomavirus (HPV) DNA in cervical specimens. A positive Nested PCR test provides presumptive evidence for the presence of HPV DNA in the specimen and provides materials suitable for direct automated DNA sequencing for HPV genotyping. We have determined that your type of device is classified as a class III device by the approval order for the VRAPAP Human Papillomavirus DNA Detection Kit dated December 23, 1988.

Section 515(a)(2) of the Act requires a class III device to have an approved PMA before it can be legally marketed, unless the device is reclassified.

Any commercial distribution of this device prior to approval of a PMA, or the effective date of any order by the Food and Drug Administration re-classifying this device into class I or II, would be a violation of the Act. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If you wish to pursue the marketing of this device and need information or assistance for preparing investigational or premarket submissions, please contact 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. We will be happy to meet with you, if you desire, to discuss any future submissions for this device. Please contact Uwe Scherf, Ph.D. at 240-276-0496 for meeting arrangements.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
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