



May 22, 2007

FILE COPY

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

Dear Dr. Lee:

Your petition requesting the Food and Drug Administration to for reclassification of the new device for "Human Papillomavirus (HPV) DNA Nested Polymerase Chain Reaction (PCR) Detection" (K063649) into a Class II category according to Section 513(f), 21 CFR 860 Subpart C, was received by this office on 05/22/2007. It was assigned docket number 2007P-0210/CCP 1 and it was filed on 05/22/2007. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2007P-0210

ACK1