

XXII Pre-market Notification Statement

I certify that, in my capacity as the Senior Manager of Regulatory Affairs and Quality Assurance, of Molecular Diagnostics Business Unit of Applied Biosystems, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patients identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



(Signature of Certifier)

Tony C. Lam

(Typed Name)

07-06-200

(Dated)

K BK010024

(Premarket Notification [510(k)] Number)