CELERA DIAGNOSTICS

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# 510(K) STATEMENT

(As required by 21 CFR 807.93)

I certify that in my capacity as Director, Regulatory and Clinical Affairs of Celera Diagnostics, 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 patient identifiers, and trade secrets and confidential information, as defined in 21 CFR 20.61.

Victoria Mackinnon

May 20, 2003

510(k) BK030033