

K083430 REAL-TIME PCR INTERNAL CONTROL 2B SETJan 15, 2009
57 days to decisionK083430 · Product code: **OLD** · Microbiology
Source: <https://www.510kdatabase.net/k083430/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Internal Polymerase Chain Reaction Control, Not Assay Specific (OLD)
Date received	Nov 19, 2008
Decision date	Jan 15, 2009
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Nanogen, Inc.
Location	San Diego, CA, US
Contact	E. JOSEPH MCMULLEN
510(k) history	2 submissions · 2 cleared · 2006-2009

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