

**K091409 LIGHTCYCLER MRSA ADVANCED TEST FOR USE  
WITH THE LIGHTCYCLER 2.0 INSTRUMENT, MODEL 05205727**Jul 6, 2010  
419 days to decisionK091409 · Product code: **NQX** · Microbiology  
Source: <https://www.510kdatabase.net/k091409/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid Amplification Test, Dna, Methicillin Resistant Staphylococcus Aureus, Direct Specimen (NQX)
Date received	May 13, 2009
Decision date	Jul 6, 2010
Days to decision	419 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Roche Molecular Systems, Inc.</b>
Location	Somerville, NJ, US
Contact	LARRY PIETRELLI
510(k) history	51 submissions · 48 cleared · 1993-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091409/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026