

K091617 QMS LIDOCAINE CALIBRATORS, MODEL 0374678Jul 17, 2009
44 days to decisionK091617 · Product code: **DLJ** · Toxicology
Source: <https://www.510kdatabase.net/k091617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Jun 3, 2009
Decision date	Jul 17, 2009
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thermo Fisher Scientific
Location	Noble Park, AU
Contact	JACK ROGERS
Website	http://www.thermofisher.com/
510(k) history	64 submissions · 64 cleared · 2007-2025

Thermo Fisher Scientific is a global life science and clinical research company based in Waltham, Massachusetts. The company operates a facility in Noble Park, Australia, providing scientific consumables, equipment, and services worldwide. Thermo Fisher has received FDA 510(k) clearances from total submissions since 2007. The company specializes primarily in Microbiology devices, which represent 89% of its regulatory submissions. Recent clearances include multiple Sensititre susceptibility systems for antimicrobial testing. The latest FDA 510(k) clearance was granted in 2...

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