

**K081378 DRI METHADONE METABOLITE (100/300) ASSAY,
CALBRATORS AND CONTROLS**Jan 14, 2009
243 days to decisionK081378 · Product code: DJR · Toxicology
Source: <https://www.510kdatabase.net/k081378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	May 16, 2008
Decision date	Jan 14, 2009
Days to decision	243 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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Device record: <https://www.510kdatabase.net/k081378/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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