

K080085 MAS TOX CONTROLApr 30, 2008
110 days to decisionK080085 · Product code: **DIF** · Toxicology
Source: <https://www.510kdatabase.net/k080085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jan 11, 2008
Decision date	Apr 30, 2008
Days to decision	110 days
Third-party review	No
Summary / Statement	Statement

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...
