

**K081083 CEDIA MYCOPHENOLIC ACID ASSAY,
CALBRATORS, MAS MYCOPHENOLIC ACID CONTROLS**Dec 19, 2008
247 days to decisionK081083 · Product code: **OAV** · Toxicology
Source: <https://www.510kdatabase.net/k081083/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mycophenolic Acid Test System (OAV) |
| Date received | Apr 16, 2008 |
| Decision date | Dec 19, 2008 |
| Days to decision | 247 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k081083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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