

**K070531 ISE MODULE AND BAR CODE READER ADDITION
FOR THE DATAPRO CLINICAL CHEMISTRY ANALYZER**Sep 4, 2007
193 days to decisionK070531 · Product code: **CGZ** · Chemistry
Source: <https://www.510kdatabase.net/k070531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion-specific, Chloride (CGZ)
Date received	Feb 23, 2007
Decision date	Sep 4, 2007
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thermo Fisher Scientific
Location	Noble Park, AU
Contact	BOLA NICHOLSON
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/k070531/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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