FDA 510(k) Premarket Notification

CLEARED

K191918 Thermo Scientific Sensititre ARIS HiQ System

Nov 6, 2019
111 days to decision

K191918 · Product code: **LRG** · Microbiology
Source: https://www.510kdatabase.net/k191918/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument For Auto Reader & Interpretation Of Overnight Suscept. Systems (LRG)
Date received	Jul 18, 2019
Decision date	Nov 6, 2019
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Thermo Fisher Scientific**
Location	Noble Park, AU
Contact	Cynthia Knapp
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...