

K053121 TRAM MODULEApr 5, 2006
149 days to decisionK053121 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k053121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 7, 2005
Decision date	Apr 5, 2006
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare
Location	Waukesha, WI, US
Contact	JOEL KENT
Website	http://www3.gehealthcare.com/en
510(k) history	168 submissions · 168 cleared · 2004-2026

GE HealthCare is an American multinational medical technology company headquartered in Waukesha, US. The company operates globally across medical imaging, ultrasound, patient care solutions, and pharmaceutical diagnostics. GE HealthCare has received FDA 510(k) clearances from total submissions since 2004. Radiology devices represent the dominant focus, accounting for 73% of regulatory submissions. The company's latest FDA 510(k) clearance was in 2026, reflecting continued innovation in medical imaging technologies. Recent cleared devices span Radiology specialties includi...
