

K052855 STARSPEED SERIES CT SCANNER SYSTEMSOct 28, 2005
17 days to decisionK052855 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k052855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Oct 11, 2005
Decision date	Oct 28, 2005
Days to decision	17 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare
Location	Waukesha, WI, US
Contact	LEKSHMI NAIR
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...
