FDA 510(k) Premarket Notification

K082761 GE LIGHTSPEED 7.2 CT SCANNER SYSTEM

CLEARED

Oct 8, 2008
16 days to decision

K082761 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k082761/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Sep 22, 2008
Decision date	Oct 8, 2008
Days to decision	16 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems, LLC**
Location	Waukesha, WI, US
Contact	TRACEY ORTIZ
Website	https://www.gehealthcare.com
510(k) history	104 submissions · 104 cleared · 2003-2026

GE Medical Systems, LLC is a medical device manufacturer based in Waukesha, US. The company specializes in Radiology devices and solutions. GE Medical Systems has received FDA 510(k) clearances from total submissions. The company's regulatory focus is entirely on Radiology devices, with a clearance history spanning from 2003 to 2026. The latest clearance in 2026 demonstrates active regulatory engagement within the past two years. Recent cleared devices include advanced imaging systems such as the Photonova Spectra series, SIGNA™ product line, AIR Recon DL, Revolution Vibe...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k082761/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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