

K031261 CARD EPMay 6, 2003
15 days to decisionK031261 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k031261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 21, 2003
Decision date	May 6, 2003
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems
Location	Milwaukee, WI, US
Contact	LARRY A KROGER
510(k) history	169 submissions · 166 cleared · 1989-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031261/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026