

K193281 Hepatic VCARMar 20, 2020
114 days to decisionK193281 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k193281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 27, 2019
Decision date	Mar 20, 2020
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems SCS
Location	Buc Cedex, FR
Contact	Lifeng Wang
510(k) history	37 submissions · 37 cleared · 2008-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193281/> 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