

K150595 SCENARIA Phase 3 Whole-body X-ray CT SystemOct 30, 2015
235 days to decisionK150595 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k150595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Mar 9, 2015
Decision date	Oct 30, 2015
Days to decision	235 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi Medical Systems America, Inc.
Location	Twinsburg, OH, US
Contact	Doug Thistlethwaite
510(k) history	100 submissions · 100 cleared · 1991-2017

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