

K091103 GUIDESHOT OPTION FOR CXR4 AND ECLOS CT SYSTEMSJun 15, 2009
60 days to decisionK091103 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k091103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 16, 2009
Decision date	Jun 15, 2009
Days to decision	60 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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