

K101888 SCENARIA WHOLE-BODY X-RAY CT SYSTEM

Apr 8, 2011
275 days to decision

K101888 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k101888/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 7, 2010
Decision date	Apr 8, 2011
Days to decision	275 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k101888/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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