

**K183291 Supria True64 Whole-Body X-Ray CT System**Feb 1, 2019  
67 days to decisionK183291 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k183291/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 26, 2018
Decision date	Feb 1, 2019
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hitachi Healthcare Americas</b>
Location	Twinsburg, OH, US
Contact	Doug Thistlethwaite
510(k) history	12 submissions · 12 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183291/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026