

**K191136 Access CT**Jul 29, 2019  
91 days to decisionK191136 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k191136/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 29, 2019
Decision date	Jul 29, 2019
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Healthcare (Suzhou) Co., Ltd.</b>
Location	Suzhou Jiangsu, CN
Contact	Ray Sun
510(k) history	17 submissions · 17 cleared · 2014-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191136/> 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 15, 2026