

**K170177 Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1**Jun 30, 2017  
162 days to decisionK170177 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k170177/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jan 19, 2017
Decision date	Jun 30, 2017
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Toshibamedical Systems Corporation</b>
Location	Tustin, CA, US
Contact	Paul Biggins
510(k) history	80 submissions · 80 cleared · 2004-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170177/> 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 16, 2026