

K161009 Aquilion ONE Vision with FIRST 2.0 (CCRS-001B) V7.4Jul 22, 2016
102 days to decisionK161009 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k161009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 11, 2016
Decision date	Jul 22, 2016
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Toshibamedical Systems Corporation
Location	Tustin, CA, US
Contact	PAUL BIGGINS
510(k) history	80 submissions · 80 cleared · 2004-2018

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