

**K201378 3D Accuitomo 150N**Feb 18, 2021  
268 days to decisionK201378 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k201378/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	May 26, 2020
Decision date	Feb 18, 2021
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>J. Morita USA, Inc.</b>
Location	Irvine, CA, US
Contact	Fujio Zushi
510(k) history	52 submissions · 52 cleared · 1988-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Fish &amp; Richardson, P.C.</b>
Contact	Keith A. Barritt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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