

**K161881 PreXion3D Excelsior**Oct 3, 2016  
87 days to decisionK161881 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k161881/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jul 8, 2016
Decision date	Oct 3, 2016
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Prexion Corporation</b>
Location	Chiyoda-Ku, JP
Contact	Shumpeita Torii
510(k) history	9 submissions · 9 cleared · 2016-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161881/> 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 27, 2026