

K232166 PreXion3D ExpeditionSep 8, 2023
49 days to decisionK232166 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k232166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jul 21, 2023
Decision date	Sep 8, 2023
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prexion Corporation
Location	Chiyoda-Ku, JP
Contact	Kenji Tanaka
510(k) history	9 submissions · 9 cleared · 2016-2023

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