

K190320 PreXion3D ExplorerApr 15, 2019
61 days to decisionK190320 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k190320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 13, 2019
Decision date	Apr 15, 2019
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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