

K203784 PreXion3D Explorer PROFeb 23, 2021
57 days to decisionK203784 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k203784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Dec 28, 2020
Decision date	Feb 23, 2021
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	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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