

K253959 Primevision 3DFeb 5, 2026
57 days to decisionK253959 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k253959/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Dec 10, 2025
Decision date	Feb 5, 2026
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply Sirona
Location	York, PA, US
Contact	Deepthi Paknikar
Website	https://www.dentsplysirona.com
510(k) history	65 submissions · 65 cleared · 2016-2026

Dentsply Sirona is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company markets products in over 120 countries and operates factories across 21 nations. Dentsply Sirona has received FDA 510(k) clearances from total submissions since 2016. Dental devices represent 78% of the company's regulatory submissions, reflecting its core focus on laboratory equipment, specialty products, and consumables including abutments, CAD/CAM blocks, and restorative materials. The company's latest clearance in 2026 demonstrates continued reg...