

K201667 Midmark Extraoral Imaging System (EOIS)Aug 6, 2020
48 days to decisionK201667 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k201667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jun 19, 2020
Decision date	Aug 6, 2020
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Midmark Corporation
Location	Torrance, CA, US
Contact	Mark Kenar
Website	http://www.midmark.com/
510(k) history	5 submissions · 5 cleared · 2016-2025

Midmark Corporation is a leading manufacturer of medical, dental, and veterinary care environment solutions with a manufacturing facility in Torrance, California. Founded in 1915, the company designs integrated equipment and systems for healthcare providers across multiple specialties. Midmark has received FDA 510(k) clearances from total submissions since 2016. The company maintains an active regulatory presence, with its most recent clearance in 2025. Its cleared devices span General Hospital sterilization systems, dental delivery and imaging equipment, and cardiovascul...
