

**K133620 CONE BEAM 3D AND 2D PANORAMIC DENTAL
IMAGING SYSTEM**May 14, 2014
170 days to decisionK133620 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k133620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Nov 25, 2013
Decision date	May 14, 2014
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imaging Sciences International
Location	Hatfield, PA, US
Contact	RUTH PUI
510(k) history	2 submissions · 2 cleared · 2014-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133620/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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