

K162085 i-CAT FLX V series / KaVo 3D eXam+ V seriesNov 10, 2016
106 days to decisionK162085 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k162085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jul 27, 2016
Decision date	Nov 10, 2016
Days to decision	106 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

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