

K160166 X-MIND triumNov 15, 2016
293 days to decisionK160166 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k160166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jan 27, 2016
Decision date	Nov 15, 2016
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	De Gotzen S.R.L.
Location	Olgiate Olona, Varese, IT
Contact	Olivier Balouka
510(k) history	5 submissions · 5 cleared · 2014-2020

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