

**K201382 X-MIND prime 3D (under trademark Acteon), I-MAX 3D
(under trademark Owandy Radiology)**Nov 18, 2020
176 days to decisionK201382 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k201382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	May 26, 2020
Decision date	Nov 18, 2020
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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