

**K203374 X-MIND prime (under trade mark Acteon), I-MAX
(under trade mark Owandy Radiology)**Feb 5, 2021
81 days to decisionK203374 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k203374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Nov 16, 2020
Decision date	Feb 5, 2021
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	De G?tzen S.R.L.
Location	Olgiate Olona, IT
Contact	Dario Bandiera
510(k) history	2 submissions · 2 cleared · 2021-2023

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