

K191719 X-MIND TriumFeb 20, 2020
239 days to decisionK191719 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k191719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jun 26, 2019
Decision date	Feb 20, 2020
Days to decision	239 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191719/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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