

**K132378 X-MIND UNITY**May 30, 2014  
303 days to decisionK132378 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k132378/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 31, 2013
Decision date	May 30, 2014
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>De Gotzen S.R.L.</b>
Location	Olgiate Olona, Varese, IT
Contact	MAURIZIO DE GOTZEN
510(k) history	5 submissions · 5 cleared · 2014-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132378/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 15, 2026