

**K200424 Giotto Class (Models - 3000X-YY and 4000X-YY)**Jun 18, 2020  
119 days to decisionK200424 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k200424/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Feb 20, 2020
Decision date	Jun 18, 2020
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ims Giotto S.P.A.</b>
Location	Sasso Marconi, IT
Contact	Antonella Rossi
510(k) history	2 submissions · 2 cleared · 2020-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200424/> 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 May 26, 2026