

K111434 GIOTTO IMAGE 3D, GIOTTO IMAGE 3D-LOct 27, 2011
157 days to decisionK111434 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k111434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	May 23, 2011
Decision date	Oct 27, 2011
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Giotto USA, LLC
Location	Carmel, IN, US
Contact	PATRICK MOONEY
510(k) history	3 submissions · 3 cleared · 2006-2012

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