

**K161229 Mammo Tomosynthesis (MDMG-5221)**May 18, 2016  
16 days to decisionK161229 · Product code: **PGY** · Radiology  
Source: <https://www.510kdatabase.net/k161229/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Display, Diagnostic Radiology (PGY)
Date received	May 2, 2016
Decision date	May 18, 2016
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Barco N.V.</b>
Location	La Jolla, CA, US
Contact	Lieven De Wandel
Website	<a href="http://www.barco.com">http://www.barco.com</a>
510(k) history	60 submissions · 60 cleared · 1998-2024

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161229/> 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 16, 2026