

**K170113 pixium 4343RCE**Feb 9, 2017  
28 days to decisionK170113 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k170113/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jan 12, 2017
Decision date	Feb 9, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Medical Systems Dmc GmbH</b>
Location	Seneca, SC, US
Contact	Ming Xiao
510(k) history	18 submissions · 18 cleared · 2013-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170113/> 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 15, 2026