

**K131766 PLATINUM DRF IMAGING SYSTEM**Dec 12, 2013  
178 days to decisionK131766 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k131766/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Jun 17, 2013
Decision date	Dec 12, 2013
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Apelem-Dms Group</b>
Location	Ashland, MA, US
Contact	Sharyn Orton
510(k) history	3 submissions · 3 cleared · 2013-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131766/> 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 27, 2026