

**K160301 Platinum dRF Imaging System**Mar 4, 2016  
29 days to decisionK160301 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k160301/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Feb 4, 2016
Decision date	Mar 4, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160301/> 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