

**K203010 Platinum dRF Imaging System**Jan 22, 2021  
113 days to decisionK203010 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k203010/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Oct 1, 2020
Decision date	Jan 22, 2021
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>MEDIcept, Inc.</b>
Contact	Scott Blood

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203010/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026