FDA 510(k) Premarket Notification

K203010 Platinum dRF Imaging System

CLEARED

Jan 22, 2021
113 days to decision

K203010 · 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	**Apelem-Dms Group**
Location	Ashland, MA, US
Contact	Samuel Sancerni
510(k) history	3 submissions · 3 cleared · 2013-2021

REGULATORY CONSULTANT

Consulting firm	**MEDIcept, Inc.**
Contact	Scott Blood

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