FDA 510(k) Premarket Notification

K201172 CFP-3131, CFP-2222

CLEARED

May 29, 2020
28 days to decision

K201172 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k201172/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	May 1, 2020
Decision date	May 29, 2020
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mx Imaging, Inc.**
Location	Torrance, CA, US
Contact	John Ross
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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