

K201172 CFP-3131, CFP-2222May 29, 2020
28 days to decisionK201172 · 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

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