

K203535 TriniasApr 28, 2021
146 days to decisionK203535 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k203535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Dec 3, 2020
Decision date	Apr 28, 2021
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shimadzu Corporation Medical Systems
Location	Kyoto, JP
Contact	Shigeru Naganishi
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203535/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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