

**K221922 Trinias**Jul 28, 2022  
27 days to decisionK221922 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k221922/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 1, 2022
Decision date	Jul 28, 2022
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shimadzu Corporation Medical Systems Division</b>
Location	Kyoto, JP
Contact	Koichi Kataoka
510(k) history	2 submissions · 2 cleared · 2022-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221922/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026