FDA 510(k) Premarket Notification

**CLEARED**

# K221922 Trinias

Jul 28, 2022
27 days to decision

K221922 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k221922/

## SUBMISSION DETAILS

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|---|---|
| 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 | **Shimadzu Corporation Medical Systems Division** |
| Location | Kyoto, JP |
| Contact | Koichi Kataoka |
| 510(k) history | 2 submissions · 2 cleared · 2022-2024 |

## 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