FDA 510(k) Premarket Notification

K211780 ZEN-2090 Turbo

CLEARED

Mar 9, 2022
273 days to decision

K211780 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k211780/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 9, 2021
Decision date	Mar 9, 2022
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Genoray Co., Ltd.**
Location	Flintville, TN, US
Contact	Sookyung Choi
510(k) history	24 submissions · 24 cleared · 2007-2026

REGULATORY CONSULTANT

Consulting firm	**Genoray America, Inc.**
Contact	Kaitlynn Min

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