FDA 510(k) Premarket Notification

K222240 EXPLORER AIR® II

CLEARED

Feb 28, 2023
217 days to decision

K222240 · Product code: **IZI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222240/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Jul 26, 2022
Decision date	Feb 28, 2023
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Surgvision GmbH**
Location	Munich, DE
Contact	Daniela Mahan
510(k) history	3 submissions · 3 cleared · 2022-2024