

**K214097 Explorer Air II**Feb 25, 2022  
59 days to decisionK214097 · Product code: **IZI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k214097/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Dec 28, 2021
Decision date	Feb 25, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214097/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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