

**K234090 EXPLORER AIR® II (8001, 8002, 8003)**Mar 20, 2024  
89 days to decisionK234090 · Product code: **IZI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k234090/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Dec 22, 2023
Decision date	Mar 20, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EXPLORER AIR® Sterile Drape (8004)

**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/k234090/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026