

**K214124 AlloX2 Pro Tissue Expanders**Jun 8, 2023  
525 days to decisionK214124 · Product code: **LCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k214124/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tissue Expander And Accessories (LCJ)
Date received	Dec 30, 2021
Decision date	Jun 8, 2023
Days to decision	525 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sientra, Inc.</b>
Location	Santa Barbara, CA, US
Contact	Denise Daljes
510(k) history	3 submissions · 3 cleared · 2020-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214124/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026