

**K200706 Sientra OPUS Silicone Gel Breast Implant Sizer**Nov 16, 2020  
243 days to decisionK200706 · Product code: **MRD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200706/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mammary Sizer (MRD)
Date received	Mar 18, 2020
Decision date	Nov 16, 2020
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sientra, Inc.</b>
Location	Santa Barbara, CA, US
Contact	JoAnn Kuhne
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/k200706/> 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