

**K232069 Expandable Lumbar Fusion Cage (Type I,Type II)**Nov 29, 2023  
140 days to decisionK232069 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k232069/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 12, 2023
Decision date	Nov 29, 2023
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai Reach Medical Instrument Co, Ltd.</b>
Location	Shanghai, CN
Contact	Jian Shen
510(k) history	3 submissions · 3 cleared · 2021-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Eva Li

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232069/> 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 25, 2026