

K242267 Gemini Medical Cage SystemOct 8, 2024
68 days to decisionK242267 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k242267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 1, 2024
Decision date	Oct 8, 2024
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ZheJiang Decans Medical Devices Co., Ltd.
Location	Jiaxing, CN
Contact	Haifeng Liu
510(k) history	6 submissions · 6 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	Sinow Medical AS
Contact	Xiaoqing Xue

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.netDevice record: <https://www.510kdatabase.net/k242267/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026