

K223776 PEEK Spinal Infusion CageMar 3, 2023
77 days to decisionK223776 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k223776/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 16, 2022
Decision date	Mar 3, 2023
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Geasure Medical Apparatus and Instruments Co., Ltd.
Location	Changzhou, CN
Contact	Jing Huang
510(k) history	4 submissions · 4 cleared · 2022-2023

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/k223776/> 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 26, 2026