

K230456 SGM Femoral Nail SystemJun 30, 2023
129 days to decisionK230456 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k230456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 21, 2023
Decision date	Jun 30, 2023
Days to decision	129 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230456/> 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