

**K232394 Internal Locking Plate and Screw Fixation System**Dec 15, 2023  
128 days to decisionK232394 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k232394/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 9, 2023
Decision date	Dec 15, 2023
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232394/> 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 26, 2026