

**K151508 IRENE Locking Compression Plate System**Feb 25, 2016  
266 days to decisionK151508 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k151508/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 4, 2015
Decision date	Feb 25, 2016
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tianjin Zhengtian Medical Instrument Co., Ltd.</b>
Location	Tianjin, CN
Contact	YIFAN FU
510(k) history	3 submissions · 3 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151508/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026