

**K112819 RECONSTRUCTION LOCKING PLATE AND 3.5MM  
LOCKING SCREW**Dec 16, 2011  
79 days to decisionK112819 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k112819/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 28, 2011
Decision date	Dec 16, 2011
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xiamen Double Engine Medical Material Co., Ltd.</b>
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112819/>; 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 18, 2026