

K130108 DOUBLE ENGINE BONE PLATE AND SCREW SYSTEMSApr 19, 2013
93 days to decisionK130108 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k130108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 16, 2013
Decision date	Apr 19, 2013
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xiamen Double Engine Medical Material Co., Ltd.
Location	Xiamen, Fujian, CN
Contact	DA ZENG
510(k) history	2 submissions · 2 cleared · 2013-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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