

**K123347 NORMED ANKLE FIX SYSTEM 4.0 AND NORMED ANKLE FIX PLUS SYSTEM 4.0**Aug 2, 2013  
275 days to decisionK123347 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k123347/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 31, 2012
Decision date	Aug 2, 2013
Days to decision	275 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Normed Medizin-Technik GmbH</b>
Location	Arlington, VA, US
Contact	DAVID C FURR
510(k) history	9 submissions · 9 cleared · 1994-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123347/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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