

**K071797 MONDEAL HAND CONTOUR SYSTEM**Sep 17, 2007  
77 days to decisionK071797 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k071797/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 2, 2007
Decision date	Sep 17, 2007
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mondeal Medical Systems GmbH</b>
Location	Amsterdam, NL
Contact	JAY EVANS
510(k) history	6 submissions · 6 cleared · 2005-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071797/> 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 19, 2026