

**K041786 CALCAMEA PLATE**Sep 8, 2004  
69 days to decisionK041786 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k041786/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 1, 2004
Decision date	Sep 8, 2004
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>New Deal, S.A.</b>
Location	Potomac, MD, US
Contact	NORMA F ESTRIN
510(k) history	28 submissions · 28 cleared · 1999-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041786/> 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 20, 2026