

**K021623 UCR SPINAL SYSTEM, 5.5MM, 8.0MM SCREWS & INSTRUMENTS**Sep 10, 2002  
117 days to decisionK021623 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k021623/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	May 16, 2002
Decision date	Sep 10, 2002
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Iame, Inc.</b>
Location	Pleasant Hill, CA, US
Contact	DAVID W SCHLERF
510(k) history	1 submissions · 1 cleared · 2002-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021623/> 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