

**K010911 MACROPORE OS SPINAL SYSTEM**Jul 20, 2001  
116 days to decisionK010911 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k010911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Mar 26, 2001
Decision date	Jul 20, 2001
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Macropore Biosurgery, Inc.</b>
Location	San Diego, CA, US
Contact	KENNETH K KLEINHENZ
510(k) history	17 submissions · 16 cleared · 2000-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010911/> 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