

**K010378 HEDROCEL VERTEBRAL BODY REPLACEMENT,  
MODEL XX-YYY-ZZZZ**Jan 28, 2002  
354 days to decisionK010378 · Product code: **MQP** · Orthopedic  
Source: <https://www.510kdatabase.net/k010378/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Feb 8, 2001
Decision date	Jan 28, 2002
Days to decision	354 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Implex Corp.</b>
Location	Allendale, NJ, US
Contact	JOHN SCHALAGO
510(k) history	65 submissions · 61 cleared · 1993-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010378/>; 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 14, 2026