

**K931686 MALLEOLAR SCREW**Apr 5, 1994  
365 days to decisionK931686 · Product code: **KTW** · Orthopedic  
Source: <https://www.510kdatabase.net/k931686/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Single Component (KTW)
Date received	Apr 5, 1993
Decision date	Apr 5, 1994
Days to decision	365 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Onyx Medical Corp.</b>
Location	Memphis, TN, US
Contact	LARAIN B GILMORE
510(k) history	47 submissions · 22 cleared · 1990-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k931686/> 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 22, 2026