

**K063497 MODIFICATION TO SCANDIUS TRITIS ABSORBABLE  
TIBIAL RECONSTRUCTION SYSTEM**Dec 19, 2006  
29 days to decisionK063497 · Product code: MAI · Orthopedic  
Source: <https://www.510kdatabase.net/k063497/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Nov 20, 2006
Decision date	Dec 19, 2006
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Scandius Biomedical, Inc.</b>
Location	Littleton, MA, US
Contact	RALPH ZIMMERMAN
510(k) history	6 submissions · 6 cleared · 2004-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063497/>. 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