

**K063499 MODIFICATION TO SCANDIUS TRITIS TIBIAL ACL
RECONSTRUCTION SYSTEM**Dec 19, 2006
29 days to decisionK063499 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k063499/>**SUBMISSION DETAILS**

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

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063499/>; Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026