K063499 MODIFICATION TO SCANDIUS TRITIS TIBIAL ACL RECONSTRUCTION SYSTEM

CLEARED

Dec 19, 2006
29 days to decision

K063499 · 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