

K133036 APOLLO SUTURE ANCHOR SYSTEM AND TITAN SCREWS

Mar 6, 2014
161 days to decision

K133036 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k133036/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 26, 2013
Decision date	Mar 6, 2014
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amendia, Inc.
Location	Apple Valley, MN, US
Contact	RICH JANSEN
510(k) history	16 submissions · 16 cleared · 2009-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k133036/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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