

**K163034 SUTUREFIX Curved Suture Anchor**Dec 7, 2016  
37 days to decisionK163034 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k163034/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Oct 31, 2016
Decision date	Dec 7, 2016
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Smith and Nephew, Inc.</b>
Location	Andover, MA, US
Contact	Anne-Marie Keefe
510(k) history	7 submissions · 7 cleared · 2016-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163034/> 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 26, 2026