

**K111716 KNOTLESS SUTURE FIXATION SYSTEM**Nov 10, 2011  
143 days to decisionK111716 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k111716/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jun 20, 2011
Decision date	Nov 10, 2011
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Core Essence Orthopaedics</b>
Location	Ft. Washington, PA, US
Contact	JEFF MILLER
510(k) history	1 submissions · 1 cleared · 2011-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111716/> 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