

**K181086 Cortical Fixation Systems**Jan 9, 2019  
259 days to decisionK181086 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k181086/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 25, 2018
Decision date	Jan 9, 2019
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cousin Biotech Sas</b>
Location	Wervicq-Sud, FR
Contact	Mathilde Collet
510(k) history	6 submissions · 6 cleared · 2008-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181086/> 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 June 21, 2026