

K191242 HEALIX ADVANCE SP BIOCOSPOSITE AnchorAug 22, 2019
105 days to decisionK191242 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k191242/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	May 9, 2019
Decision date	Aug 22, 2019
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medos International SARL
Location	Raynham, MA, US
Contact	Elizabeth Messana
510(k) history	96 submissions · 96 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191242/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026