

K203794 HEALIX Ti Dual Threaded Suture Anchor with DYNATAPE SutureFeb 1, 2021
35 days to decisionK203794 · Product code: MBI · Orthopedic
Source: <https://www.510kdatabase.net/k203794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 28, 2020
Decision date	Feb 1, 2021
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Depuy Synthes Mitek, A Johnson & Johnson Company
Contact	Elizabeth Messana

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203794/>; 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 14, 2026