

K221364 Mitek TIGHT-N AnchorJul 11, 2022
61 days to decisionK221364 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k221364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 11, 2022
Decision date	Jul 11, 2022
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Depuy Synthes Mitek Sports Medicine
Contact	Ashley Aromando (Goncalo)

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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