

**K212381 VersaTap, VersaLat, DueLock, VersaTi, MiniTi**Dec 6, 2021  
126 days to decisionK212381 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k212381/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 2, 2021
Decision date	Dec 6, 2021
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ortho-Design (Pty), Ltd.</b>
Location	Pretoria, ZA
Contact	Dian Peach
510(k) history	2 submissions · 2 cleared · 2021-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Jalex Medical</b>
Contact	Daniel Johnson

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212381/> 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 26, 2026