

K213104 Auxilock Titanium Screw-In Suture AnchorJul 29, 2022
308 days to decisionK213104 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k213104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 24, 2021
Decision date	Jul 29, 2022
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Auxein Medical Private Limited
Location	Sonipat, IN
Contact	Rahul Luthra
510(k) history	12 submissions · 12 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213104/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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