

**K213110 AUXILOCK PEEK OPTIMA Screw-In Suture Anchor,
AUXILOCK ROTADOR PEEK OPTIMA Screw-In Anchor**Dec 16, 2022
448 days to decisionK213110 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k213110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 24, 2021
Decision date	Dec 16, 2022
Days to decision	448 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

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