FDA 510(k) Premarket Notification

K213018 Auxilock GFS Mini, GFS II Large, and GFS Ultimate

CLEARED

Nov 18, 2022
424 days to decision

K213018 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k213018/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 20, 2021
Decision date	Nov 18, 2022
Days to decision	424 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