FDA 510(k) Premarket Notification

CLEARED

K230492 Avitus® Precision Autograft Delivery System

Jun 26, 2023
123 days to decision

K230492 · Product code: **FMF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230492/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Feb 23, 2023
Decision date	Jun 26, 2023
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Avitus Orthopaedics, Inc.**
Location	Farmington, CT, US
Contact	Maxim Budyansky
510(k) history	5 submissions · 5 cleared · 2015-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230492/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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