

K231456 Avitus® DragonWing Large Volume Autograft Delivery System

Jul 17, 2023
59 days to decisionK231456 · Product code: **FMF** · Orthopedic
Source: <https://www.510kdatabase.net/k231456/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	May 19, 2023
Decision date	Jul 17, 2023
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Keystone Regulatory Services, LLC
Contact	Robert McLain

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231456/> 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 27, 2026