FDA 510(k) Premarket Notification

K210631 Avitus(r) Bone Harvester

CLEARED

Mar 31, 2021
28 days to decision

K210631 · Product code: **KNW** · Orthopedic
Source: https://www.510kdatabase.net/k210631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 3, 2021
Decision date	Mar 31, 2021
Days to decision	28 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	William McLain

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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Device record: https://www.510kdatabase.net/k210631/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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