FDA 510(k) Premarket Notification

K190290 AltiVate Reverse Humeral Stem, 48mm

CLEARED

Apr 26, 2019
74 days to decision

K190290 · Product code: **KWS** · Orthopedic
Source: https://www.510kdatabase.net/k190290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Feb 11, 2019
Decision date	Apr 26, 2019
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Encore Medical, L.P.**
Location	Austin, TX, US
Contact	Teffany Hutto
510(k) history	81 submissions · 81 cleared · 2002-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190290/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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