

K183317 AdvantageRib SystemFeb 14, 2019
76 days to decisionK183317 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k183317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Nov 30, 2018
Decision date	Feb 14, 2019
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sig Medical Corporation
Location	Hershey, PA, US
Contact	Andrew Davison
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Jalex Medical, LLC
Contact	Lauren Smith

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183317/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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