

K202326 BESPACharcot SystemNov 9, 2021
449 days to decisionK202326 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k202326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 17, 2020
Decision date	Nov 9, 2021
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bespa Global, LLC
Location	Cape Elizabeth, ME, US
Contact	Lisa Viele
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Kapstone Medical, LLC
Contact	Katelyn Jessup

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

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