FDA 510(k) Premarket Notification

K202326 BESPA Charcot System

CLEARED

Nov 9, 2021
449 days to decision

K202326 · 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