FDA 510(k) Premarket Notification

K190430 OsteoCentric Bone Plate and Screw System

CLEARED

Mar 22, 2019
28 days to decision

K190430 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k190430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 22, 2019
Decision date	Mar 22, 2019
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osteocentric Trauma**
Location	Austin, TX, US
Contact	Todd Evans
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Empirical Consulting, LLC**
Contact	Meredith Lee May

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