FDA 510(k) Premarket Notification

K210247 OsteoCentric Integrated Hip Fastener System

CLEARED

Apr 30, 2021
91 days to decision

K210247 · Product code: **JDO** · Orthopedic
Source: https://www.510kdatabase.net/k210247/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fixation, Proximal Femoral, Implant (JDO)
Date received	Jan 29, 2021
Decision date	Apr 30, 2021
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osteocentric Technologies D.B.A. Osteocentric Trauma**
Location	Logan, UT, US
Contact	Todd Evans
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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