FDA 510(k) Premarket Notification

CLEARED

K212545 FlexitSystem Knee osteotomy system

Feb 11, 2022
183 days to decision

K212545 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k212545/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 12, 2021
Decision date	Feb 11, 2022
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neosteo**
Location	Round Rock, TX, US
Contact	JD Webb
510(k) history	6 submissions · 6 cleared · 2013-2022

REGULATORY CONSULTANT

Consulting firm	**The OrthoMedix Group, Inc.**
Contact	JD Webb

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