FDA 510(k) Premarket Notification

K192394 Hi-Fatigue Bone Cement

CLEARED

Dec 2, 2019
90 days to decision

K192394 · Product code: **LOD** · Orthopedic
Source: https://www.510kdatabase.net/k192394/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement (LOD)
Date received	Sep 3, 2019
Decision date	Dec 2, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osartis GmbH**
Location	Dieburg, DE
Contact	Volker Stirnal
510(k) history	6 submissions · 6 cleared · 2019-2024