FDA 510(k) Premarket Notification

K192449 Joline Kyphoplasty System Allevo

CLEARED

May 27, 2020
264 days to decision

K192449 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k192449/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Sep 6, 2019
Decision date	May 27, 2020
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Joline GmbH & Co. KG**
Location	Hechingen, DE
Contact	Peter Kohlbecher
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert A Poggie

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