FDA 510(k) Premarket Notification

CLEARED

K192403 VK100 Percutaneous Vertebral Augmentation System

Nov 8, 2019
66 days to decision

K192403 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k192403/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Sep 3, 2019
Decision date	Nov 8, 2019
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bonwrx, Ltd.**
Location	Lansing, MI, US
Contact	Ralph W. Carmichael
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Msquared Associates, Inc.**
Contact	Connie Qiu

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