FDA 510(k) Premarket Notification

K191709 V-STRUT Vertebral Implant

CLEARED

Mar 5, 2020
253 days to decision

K191709 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k191709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jun 26, 2019
Decision date	Mar 5, 2020
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hyprevention Sas**
Location	Pessac Cedex, FR
Contact	Cecile Vienney
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Hyprevention, Inc.**
Contact	Cecile Vivez Vienney

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