

K191709 V-STRUT Vertebral ImplantMar 5, 2020
253 days to decisionK191709 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191709/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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