

K181262 SpineJack Expansion KitAug 30, 2018
111 days to decisionK181262 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k181262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	May 11, 2018
Decision date	Aug 30, 2018
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vexim SA
Location	Balma, FR
Contact	Vincent Gardes
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

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

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