

K211238 SpineJack Expansion Kit, Vertaplex Radiopaque Bone Cement, Vertaplex HV Radiopaque Bone Cement

Jun 25, 2021
60 days to decision

K211238 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k211238/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Apr 26, 2021
Decision date	Jun 25, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Instruments
Location	Kalamazoo, MI, US
Contact	Susanne Galin
510(k) history	72 submissions · 72 cleared · 1994-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k211238/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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