FDA 510(k) Premarket Notification

K223294 SpineJack® Expansion Kit

CLEARED

Dec 20, 2022
55 days to decision

K223294 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k223294/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Oct 26, 2022
Decision date	Dec 20, 2022
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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