FDA 510(k) Premarket Notification

K202393 SpineJack Expansion Kit

CLEARED

Oct 20, 2020
60 days to decision

K202393 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k202393/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Aug 21, 2020
Decision date	Oct 20, 2020
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	Kristi Ashton
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...