FDA 510(k) Premarket Notification

CLEARED

K150582 Vertaplex® High Viscosity (HV) Radiopaque Bone Cement

Jun 12, 2015
95 days to decision

K150582 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k150582/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Mar 9, 2015
Decision date	Jun 12, 2015
Days to decision	95 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...