FDA 510(k) Premarket Notification

CLEARED

K002652 SURGICAL SIMPLEX P RADIOPAQUE BONE CEMENT AND ACM AND MIXEVACII

Jan 26, 2001
154 days to decision

K002652 · Product code: **LOD** · Orthopedic
Source: https://www.510kdatabase.net/k002652/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement (LOD)
Date received	Aug 25, 2000
Decision date	Jan 26, 2001
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	SUZANNE VELAZQUEZ
510(k) history	124 submissions · 121 cleared · 1976-2023

Stryker Corp. is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, implants, and patient safety technologies used globally across multiple medical specialties. Stryker has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company maintains active regulatory engagement, with its latest clearance in 2023. Its product portfolio spans orthopedic devices, neurosurgical implants, surgical instruments, and endoscopy systems, reflecting a broad pr...