FDA 510(k) Premarket Notification

CLEARED

K912190 STRYKER HIGH VACUUM BONE CEMENT MIXER/INJECT SYST

Aug 29, 1991
104 days to decision

K912190 · Product code: **JDZ** · Orthopedic
Source: https://www.510kdatabase.net/k912190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixer, Cement, For Clinical Use (JDZ)
Date received	May 17, 1991
Decision date	Aug 29, 1991
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	HARMON H WOODWORTH
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...