CLEARED

K102885 HOFFMANN II EXTERNAL FIXATION SYSTEM LINE EXTENSION MODEL 4920-1-010, 4920-1-020, 4920-1-030, 4920-1-100, HOFFMANN II EX

Jan 14, 2011
106 days to decision

K102885 · Product code: **JEC** · Orthopedic
Source: https://www.510kdatabase.net/k102885/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Component, Traction, Invasive (JEC)
Date received	Sep 30, 2010
Decision date	Jan 14, 2011
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	ZAMIR BAR-DAVID
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...