

K943589 STRYKER TOTAL PERFORMANCE SYSTEMDec 15, 1994
146 days to decisionK943589 · Product code: **HWE** · Orthopedic
Source: <https://www.510kdatabase.net/k943589/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Surgical, Orthopedic, Ac-powered Motor And Accessory/attachment (HWE)
Date received	Jul 22, 1994
Decision date	Dec 15, 1994
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corp.
Location	Mchenry, IL, US
Contact	TAMMY LOUNDS
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...

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