FDA 510(k) Premarket Notification

K110476 AXSOS (TM) LOCKING PLATE SYSTEM

CLEARED

Mar 18, 2011
28 days to decision

K110476 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k110476/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 18, 2011
Decision date	Mar 18, 2011
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	ESTELA CELI
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k110476/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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