

**K920193 OMNIFLEX M-HA HIP STEM SERIES**Jun 8, 1992  
145 days to decisionK920193 · Product code: **KWL** · Orthopedic  
Source: <https://www.510kdatabase.net/k920193/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Jan 15, 1992
Decision date	Jun 8, 1992
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker Corp.</b>
Location	Mchenry, IL, US
Contact	ROBERT A KOCH
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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