FDA 510(k) Premarket Notification

K940710 STRYKER MICRODEBRIDER SYSTEM

CLEARED

May 16, 1994
88 days to decision

K940710 · Product code: **ERL** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k940710/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Feb 17, 1994
Decision date	May 16, 1994
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	JEFF KABLIK
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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Device record: https://www.510kdatabase.net/k940710/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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