

K943569 STRYKER TOTAL PERFORMANCE SYSTEMJan 9, 1995
171 days to decisionK943569 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k943569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Jul 22, 1994
Decision date	Jan 9, 1995
Days to decision	171 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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943569/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026