

K944393 STRYKER STERI-SHIELD SURGICAL APPARELAug 28, 1995
353 days to decisionK944393 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k944393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 9, 1994
Decision date	Aug 28, 1995
Days to decision	353 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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