

**K141095 STRYKER STERI-SHIELD FLYTE HYBRID TOGAS**Aug 26, 2014  
120 days to decisionK141095 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k141095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gown, Surgical (FYA)
Date received	Apr 28, 2014
Decision date	Aug 26, 2014
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker Corporation</b>
Location	Malwah, NJ, US
Contact	JULIA HELGESON
Website	<a href="http://www.stryker.com/">http://www.stryker.com/</a>
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...

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