

K200493 Stryker T7 Surgical Hoods, Stryker T7 Surgical Togas, Zippered, Stryker T7 Surgical Togas, Zippered with Peel Away Face Shield, Stryker T7 Surgical Togas, PulloverMar 21, 2020
22 days to decisionK200493 · Product code: FXY · General Hospital
Source: <https://www.510kdatabase.net/k200493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hood, Surgical (FXY)
Date received	Feb 28, 2020
Decision date	Mar 21, 2020
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Stryker Corporation
Location	Malwah, NJ, US
Contact	Corinne Larke-Grass
Website	http://www.stryker.com/
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...
