

K140588 FLYTE HYBRID HOOD, FLYTE HYBRID HOOD WITH PEELAWAY LENSJun 26, 2014
111 days to decisionK140588 · Product code: FXY · General Hospital
Source: <https://www.510kdatabase.net/k140588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hood, Surgical (FXY)
Date received	Mar 7, 2014
Decision date	Jun 26, 2014
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corporation
Location	Malwah, NJ, US
Contact	JULIA HELGESON
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...

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