FDA 510(k) Premarket Notification

CLEARED

K151932 Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing

Mar 31, 2016
261 days to decision

K151932 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k151932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jul 14, 2015
Decision date	Mar 31, 2016
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	SOMI EKWEALOR
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...