FDA 510(k) Premarket Notification

K914053 SYSTEM 350

CLEARED

Sep 25, 1992
382 days to decision

K914053 · Product code: **CAC** · Anesthesiology
Source: https://www.510kdatabase.net/k914053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Sep 9, 1991
Decision date	Sep 25, 1992
Days to decision	382 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	BERTHA ERLENBUSH
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...