FDA 510(k) Premarket Notification

K955599 STRYKER FEMORAL CANAL SPONGE & ACETABULUM SPONGE

CLEARED

Feb 22, 1996
76 days to decision

K955599 · Product code: **GDY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k955599/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Dec 8, 1995
Decision date	Feb 22, 1996
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	TAMMY LOUNDS
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...