FDA 510(k) Premarket Notification

CLEARED

K954726 STRYKER STRYKEFLOW SUCTION IRRIGATOR (MODIFICATION)

Nov 29, 1995
118 days to decision

K954726 · Product code: **GCX** · General Hospital
Source: https://www.510kdatabase.net/k954726/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Suction, Operating-room, Wall Vacuum Powered (GCX)
Date received	Aug 3, 1995
Decision date	Nov 29, 1995
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Endoscopy**
Location	San Jose, CA, US
Contact	CHARLES L NELSON
Website	https://www.stryker.com
510(k) history	101 submissions · 101 cleared · 1993-2026

Stryker Endoscopy is a medical device manufacturer based in San Jose, US. The company specializes in endoscopic and surgical imaging systems for minimally invasive procedures. Stryker Endoscopy has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with its latest clearance in 2026. Its portfolio spans General & Plastic Surgery devices, orthopedic surgical tools, and obstetric and gynecologic instruments. Recent cleared devices include advanced imaging systems such as 4K camera platforms...