FDA 510(k) Premarket Notification

CLEARED

K241401 Connected OR Hub with Device and Voice Control

Aug 15, 2024
90 days to decision

K241401 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241401/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	May 17, 2024
Decision date	Aug 15, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SDC4K Information Management System with Device and Voice Control

APPLICANT

Company	**Stryker Endoscopy**
Location	San Jose, CA, US
Contact	Sekar Divya
Website	https://www.stryker.com
510(k) history	99 submissions · 99 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...