

K220108 SDC4K Information Management System with Device and Voice Control Package

Feb 9, 2022
27 days to decisionK220108 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220108/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jan 13, 2022
Decision date	Feb 9, 2022
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Endoscopy
Location	San Jose, CA, US
Contact	Divya Sekar
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...