

K230886 Connected OR Hub with Device and Voice ControlJun 21, 2023
82 days to decisionK230886 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k230886/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Mar 31, 2023
Decision date	Jun 21, 2023
Days to decision	82 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	Lauren Bentley
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...

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