FDA 510(k) Premarket Notification

CLEARED

K233327 1788 4K Camera System with Advanced Imaging Modality

Jan 9, 2024
102 days to decision

K233327 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233327/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 29, 2023
Decision date	Jan 9, 2024
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Endoscopy**
Location	San Jose, CA, US
Contact	Michelle Stephens
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...