FDA 510(k) Premarket Notification

K041305 STRYKER BIOZIP SUTURE ANCHOR SYSTEM

CLEARED

Jun 14, 2004
28 days to decision

K041305 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k041305/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	May 17, 2004
Decision date	Jun 14, 2004
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Endoscopy**
Location	San Jose, CA, US
Contact	MELISSA MURPHY
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...