FDA 510(k) Premarket Notification

K240407 ICONIX All-Suture Anchor

CLEARED

Mar 7, 2024
27 days to decision

K240407 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k240407/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Feb 9, 2024
Decision date	Mar 7, 2024
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ICONIX TT All-Suture Anchor; ICONIX with Needles All-Suture Anchor

APPLICANT

Company	**Stryker Endoscopy**
Location	San Jose, CA, US
Contact	Matt Corbett
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...