FDA 510(k) Premarket Notification

CLEARED

K262369 AIR+ All-Inside Meniscal Repair Device, Curved Up

Jul 30, 2026
20 days to decision

K262369 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k262369/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jul 10, 2026
Decision date	Jul 30, 2026
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	AIR+ All-Inside Meniscal Repair Device, Curved Down

APPLICANT

Company	**Stryker Endoscopy**
Location	San Jose, CA, US
Contact	Katie Farraro
Website	https://www.stryker.com
510(k) history	103 submissions · 102 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...