FDA 510(k) Premarket Notification

# K253888 MOLLI 2 System

**CLEARED**

Dec 31, 2025
27 days to decision

K253888 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253888/

**SUBMISSION DETAILS**

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Marker, Radiographic, Implantable (NEU) |
| Date received | Dec 4, 2025 |
| Decision date | Dec 31, 2025 |
| Days to decision | 27 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...