

K252247 Injector Force Max Single Use Injector (NM-400L)Oct 16, 2025
90 days to decisionK252247 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jul 18, 2025
Decision date	Oct 16, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Injector Force Max Single Use Injector (NM-400U); Injector Force Max Single Use Injector (NM-400Y); Injector Force Max Single Use Injector (NM-401L)

APPLICANT

Company	Olympus Medical Systems Corporation
Location	Melville, NY, US
Contact	Seiko Yunoki
510(k) history	81 submissions · 81 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	Olympus Surgical Technologies of America
Contact	Jillian Connery

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252247/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026