FDA 510(k) Premarket Notification

CLEARED

K251542 InstaFAN

Jul 18, 2025
59 days to decision

K251542 · Product code: **ODG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k251542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	May 20, 2025
Decision date	Jul 18, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Onepass Medical , Ltd.**
Location	Katzrin, IL
Contact	Jacob Ben Arie
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**MRC Global**
Contact	Danielle Besal

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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