FDA 510(k) Premarket Notification

K250187 Disposable Hot Biopsy Forceps (FD-210U)

CLEARED

Oct 7, 2025
258 days to decision

K250187 · Product code: **KGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250187/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Forceps, Biopsy, Electric (KGE)
Date received	Jan 22, 2025
Decision date	Oct 7, 2025
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Disposable Hot Biopsy Forceps (FD-230U)

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	Susan Lewandowski

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k250187/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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