FDA 510(k) Premarket Notification

K242228 Triopsy Actuator (TMSDGB)

CLEARED

Jan 10, 2025
164 days to decision

K242228 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k242228/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 30, 2024
Decision date	Jan 10, 2025
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Triopsy Biopsy Needle (BN-1825-36-01); Triopsy Biopsy Needle (BN-1825-55-01)

APPLICANT

Company	**Triopsy Medical, Inc.**
Location	Mankato, MN, US
Contact	David Bostwick
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Eri Group**
Contact	John Mann

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