

K240057 TraumaGuard Intra-abdominal Pressure Sensing System

Apr 17, 2024
100 days to decision

K240057 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k240057/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jan 8, 2024
Decision date	Apr 17, 2024
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sentinel Medical Technologies, LLC
Location	Jacksonville, FL, US
Contact	Robert Mueller
510(k) history	2 submissions · 2 cleared · 2021-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k240057/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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