

K210570 TraumaGuard Intra-abdominal Pressure Sensing System

Oct 29, 2021
245 days to decisionK210570 · Product code: **PHU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k210570/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intra-abdominal Pressure Monitoring Device (PHU)
Date received	Feb 26, 2021
Decision date	Oct 29, 2021
Days to decision	245 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

REGULATORY CONSULTANT

Consulting firm	Tpl Consulting
Contact	Darci Diage

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/k210570/>. 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 25, 2026