FDA 510(k) Premarket Notification

CLEARED

K210570 TraumaGuard Intra-abdominal Pressure Sensing System

Oct 29, 2021
245 days to decision

K210570 · 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