

K221139 Bodygard SFS Surgical Gown Level 4Nov 10, 2022
205 days to decisionK221139 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k221139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Apr 19, 2022
Decision date	Nov 10, 2022
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Feliks Plastik Laminasyon VE Ambalaj Malzemeleri
Location	Odunpazari, TR
Contact	Ali Serdar Serteser
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Dp Distribution & Consulting, LLC
Contact	Darren Reeves

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/k221139/> 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 26, 2026