

K202845 Bodygard SFS Surgical Gown Level 3Feb 24, 2022
517 days to decisionK202845 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k202845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 25, 2020
Decision date	Feb 24, 2022
Days to decision	517 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Feliks Plastik Laminasyon VE Ambalaj Malzemeleri Sanayi
Location	Eskisehir, TR
Contact	Ali Serdar Serteser
510(k) history	2 submissions · 2 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/k202845/> 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 27, 2026