

K213844 Surgical GownFeb 16, 2023
434 days to decisionK213844 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k213844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Dec 9, 2021
Decision date	Feb 16, 2023
Days to decision	434 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bayteks Teknik Tekstil San. VE Tic. A.S.
Location	Merkez, TR
Contact	Spero Hegbe
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Emergo by UL
Contact	Sarah Marie Fitzgerald

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/k213844/> 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