

K211399 Sterile Level 3 Surgical GownJul 22, 2022
443 days to decisionK211399 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k211399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	May 5, 2021
Decision date	Jul 22, 2022
Days to decision	443 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Barco Tekstil Sanayi VE Ticaret A.S.
Location	Istanbul, TR
Contact	Emre Gomruk
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Medcer Uluslararası Medikal Belgelendirme A.S.
Contact	Mehmet Fatih Örmeci

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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