

K230577 Sterile Triplex Surgical Gown (S, M, L, XL, XXL, XXXL)Aug 16, 2023
168 days to decisionK230577 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k230577/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 1, 2023
Decision date	Aug 16, 2023
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Medcare Saglik Urunleri Sanayi VE Ticaret Anonim Sirketi
Location	Izmir, TR
Contact	Muge Ersahin
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Iuvo Consulting, LLC
Contact	Rhonda Alexander

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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