

**K210148 Flosteril Poly-reinforced Isolation Gowns Model 8120 (Catalogue Number 8120400), Flosteril Poly-reinforced Isolation Gowns Model (Catalogue Number 8120410), Flosteril Poly-reinforced Isolation Gowns Model (Catalogue Number 8120430), Flosteril Poly-reinforced Isolation Gowns Model (Catalogue Number 8120450), Flosteril Poly-reinforced Isolation Gowns Model (Catalogue Number 8120460)**

Apr 13, 2022  
447 days to decision

K210148 · Product code: FYC · General Hospital  
Source: <https://www.510kdatabase.net/k210148/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Jan 21, 2021
Decision date	Apr 13, 2022
Days to decision	447 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Flomak Tekstil Makine Muh. Mum. Taah. San. Tic. Ltd. Sti.</b>
Location	Istanbul, TR
Contact	Alaattin Saz
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mansour Consulting, LLC</b>
Contact	Jay Mansour

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.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k210148/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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