CLEARED

Apr 13, 2022
447 days to decision

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)

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

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Mansour Consulting, LLC**
Contact	Jay Mansour

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