

K201351 Maxima Surgical GownMar 11, 2022
659 days to decisionK201351 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k201351/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	May 21, 2020
Decision date	Mar 11, 2022
Days to decision	659 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elevate Textiles
Location	Mt. Holly, NC, US
Contact	Nathaniel Terry
Website	http://www.itg-global.com/
510(k) history	1 submissions · 1 cleared · 2022-2022

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