

K200977 Modular TogaAug 5, 2020
114 days to decisionK200977 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k200977/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Apr 13, 2020
Decision date	Aug 5, 2020
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Operating Room Innovations, Inc.
Location	San Diego, CA, US
Contact	Mark McBride
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Accurate Consultants, Inc.
Contact	Glen Feye

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200977/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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