

K192560 Surgical GownMay 22, 2020
248 days to decisionK192560 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k192560/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 17, 2019
Decision date	May 22, 2020
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shandong Kangli Medical Equipment Technology Co., Ltd.
Location	Zaozhuang, CN
Contact	Zhuang Liu
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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