

K220435 SEJONG Surgical Gown SoftFeb 10, 2023
361 days to decisionK220435 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k220435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Feb 14, 2022
Decision date	Feb 10, 2023
Days to decision	361 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sejong Healthcare Co., Ltd.
Location	Paju ?Si, KR
Contact	Bong Sung Lee
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	K-Bio Solutions
Contact	Seohee Kwon

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.netDevice record: <https://www.510kdatabase.net/k220435/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026