

K230838 Cardinal Health™ SmartGown™ EDGE Breathable Surgical Gown with ASSIST™ Instrument PocketsJul 27, 2023
122 days to decisionK230838 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k230838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 27, 2023
Decision date	Jul 27, 2023
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Cardinal Health200, LLC
Location	Waukegan, IL, US
Contact	Emily Hunter
510(k) history	26 submissions · 26 cleared · 2011-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230838/> 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 14, 2026