

K200824 Cardinal Health SMARTGOWN Breathable Surgical Gown, Cardinal Health SMARTGOWN AIR Breathable Surgical Gown

Jul 29, 2020
121 days to decision

K200824 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k200824/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 30, 2020
Decision date	Jul 29, 2020
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k200824/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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