

K190306 AMD Ritmed AssureWear VersaGownJan 17, 2020
339 days to decisionK190306 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k190306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Feb 12, 2019
Decision date	Jan 17, 2020
Days to decision	339 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amd Medicom, Inc.
Location	Pointe-Claire, Montreal, CA
Contact	Ronald Reuben
510(k) history	2 submissions · 2 cleared · 2019-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190306/> 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 June 29, 2026