

K223259 coactiv+™ Antimicrobial Wound GelMay 24, 2023
212 days to decisionK223259 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Oct 24, 2022
Decision date	May 24, 2023
Days to decision	212 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kane Biotech, Inc.
Location	Winnipeg, CA
Contact	Lori Christofalos
510(k) history	3 submissions · 3 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Albert Rego, PhD, Inc.
Contact	Albert Rego

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/k223259/> 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 26, 2026