

K213970 D-Care Surgical Face Mask 3 Ply, D-Care Medical Face Mask 3 PlyJan 23, 2022
34 days to decisionK213970 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k213970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 20, 2021
Decision date	Jan 23, 2022
Days to decision	34 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Danameco Medical Joint Stock Corporation
Location	Da Nang, VN
Contact	Huynh Thi Li Li
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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/k213970/>. 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