

K202096 3-ply EcoGuard B with Earloop, 3-ply EcoGuard B with Tie-OnFeb 2, 2021
188 days to decisionK202096 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k202096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 29, 2020
Decision date	Feb 2, 2021
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ecoguard, Inc.
Location	Grover, NC, US
Contact	Fang Wang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Nickita Alexiades

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/k202096/> 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