

K153409 Protect U Guard Earloop and Tie-On Mask (Blue, White or Green)Nov 15, 2016
356 days to decisionK153409 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k153409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Nov 25, 2015
Decision date	Nov 15, 2016
Days to decision	356 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Protect U Guard, LLC
Location	Safety Harbor, FL, US
Contact	Brent W. Laartz
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153409/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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