

K230380 Surgical Face Masks, Model: EFMDS-L50Pn BLUAug 3, 2023
171 days to decisionK230380 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k230380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 13, 2023
Decision date	Aug 3, 2023
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Iris USA
Location	Pleasant Prairie, WI, US
Contact	Michael Cruz
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230380/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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