

K192374 Cardinal Health™ Level 3 Surgical Mask with Anti-Fog Foam StripDec 2, 2019
94 days to decisionK192374 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k192374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 30, 2019
Decision date	Dec 2, 2019
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardinal Health200, LLC
Location	Waukegan, IL, US
Contact	Dominic Tunzi
510(k) history	26 submissions · 26 cleared · 2011-2024

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