

K152197 Skypro, SP01 MaskAug 26, 2016
387 days to decisionK152197 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k152197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 5, 2015
Decision date	Aug 26, 2016
Days to decision	387 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Skypro Medical Supplies Company
Location	Hong Kong, CN
Contact	Cyrus Wong
510(k) history	3 submissions · 3 cleared · 2016-2023

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