

K213406 Savvy Mask - Level 3 Surgical Face MaskNov 18, 2021
30 days to decisionK213406 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k213406/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 19, 2021
Decision date	Nov 18, 2021
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Texas Medplast, LLC
Location	Houston, TX, US
Contact	Diego Olmos
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213406/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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