

**K210513 UNIWEB Surgical Mask, Model: ASTM Level 1,  
UNIWEB Surgical Mask, Model: ASTM Level 2**Sep 29, 2021  
218 days to decisionK210513 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k210513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 23, 2021
Decision date	Sep 29, 2021
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Universal Incorporation</b>
Location	Taipei City, TW
Contact	Mei-Hui Huang
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Voler Biotech Consulting CO., Ltd.</b>
Contact	Tyra Chiu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210513/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026