

**K211771 The GOOD High Fluid-Resistant Surgical Mask, The GOOD High Fluid-Resistant Surgical Procedure KF Mask, The GOOD Super Guard Design High Fluid-Resistant Surgical Mask, The KOEASY High Fluid-Resistant Surgical Mask, The KOEASY High Fluid-Resistant Surgical Procedure KF Mask, The KOEASY Super Guard Design High Fluid-Resistant Surgical Mask**Aug 24, 2022  
442 days to decisionK211771 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k211771/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 8, 2021
Decision date	Aug 24, 2022
Days to decision	442 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>The Good Corporation</b>
Location	Pyeongtaek-Si, KR
Contact	Hak Rae Lee
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>K-Bio Solutions</b>
Contact	Mikael Hellstrand

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

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