

K210761 Velguard Surgical Face MaskJul 16, 2021
123 days to decisionK210761 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210761/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Mar 15, 2021 |
| Decision date | Jul 16, 2021 |
| Days to decision | 123 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Esstee Exports Health Care Division |
| Location | Tirupur, IN |
| Contact | Zachary Wilson |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------------|
| Consulting firm | Pathmaker FDA Law, PLLC |
| Contact | Amy Fowler |

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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