

**K812675 DISPOSABLE SURGICAL FACE MASKS**Oct 13, 1981  
21 days to decisionK812675 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k812675/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 22, 1981
Decision date	Oct 13, 1981
Days to decision	21 days
Third-party review	No

**APPLICANT**

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Company	<b>Irema USA , Ltd.</b>
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1981-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k812675/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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