

**K875172 DISPOSABLE SURGICAL FACE MASK**Jan 22, 1988  
36 days to decisionK875172 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k875172/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 17, 1987
Decision date	Jan 22, 1988
Days to decision	36 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k875172/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 9, 2026