

**K832194 SURGICAL FACE MASK-DISPOSABLE**Jul 26, 1983  
18 days to decisionK832194 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k832194/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 8, 1983
Decision date	Jul 26, 1983
Days to decision	18 days
Third-party review	No

**APPLICANT**

---

Company	<b>Tecnol New Jersey Wound Care, Inc.</b>
Location	Hammonton, NJ, US
510(k) history	35 submissions · 34 cleared · 1976-1991

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k832194/>; 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 May 22, 2026