

**K946343 INTEC EXTENDED EYE SHIELD WITH MASK**Mar 22, 1995  
82 days to decisionK946343 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k946343/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 30, 1994
Decision date	Mar 22, 1995
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Intec Industries, Inc.</b>
Location	Birmingham, AL, US
Contact	FRANK LEE
510(k) history	2 submissions · 2 cleared · 1995-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k946343/> 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 6, 2026