

**K120244 SPECTRASHIELD 9500 SURGICAL N95 RESPIRATOR**Jul 5, 2012  
160 days to decisionK120244 · Product code: **ONT** · General Hospital  
Source: <https://www.510kdatabase.net/k120244/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	N95 Respirator With Antimicrobial/antiviral Agent (ONT)
Date received	Jan 27, 2012
Decision date	Jul 5, 2012
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nexera Medical, Inc.</b>
Location	Oakland Park, FL, US
Contact	PAUL SALLARULO
510(k) history	3 submissions · 3 cleared · 2011-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120244/> 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 June 3, 2026