

K150729 SpectraShield 9500 Surgical N95 RespiratorDec 29, 2015
284 days to decisionK150729 · Product code: **ONT** · General Hospital
Source: <https://www.510kdatabase.net/k150729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	N95 Respirator With Antimicrobial/antiviral Agent (ONT)
Date received	Mar 20, 2015
Decision date	Dec 29, 2015
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nexera Medical, Inc.
Location	Oakland Park, FL, US
Contact	Paul Sallarulo
510(k) history	3 submissions · 3 cleared · 2011-2015

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