

**K063747 INOVEL HEALTH CARE N95 PARTICULATE  
RESPIRATORS AND SURGICAL MASKS, MODELS MFRN95-S,  
MFRN95-XS, MFRN95-ML, MFRN95-A**Jan 12, 2007  
24 days to decisionK063747 · Product code: **MSH** · General Hospital  
Source: <https://www.510kdatabase.net/k063747/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respirator, Surgical (MSH)
Date received	Dec 19, 2006
Decision date	Jan 12, 2007
Days to decision	24 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inovel, LLC</b>
Location	Culver City, CA, US
Contact	WILLIAM WARZYNIAK
510(k) history	5 submissions · 5 cleared · 2004-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063747/>; 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 29, 2026