

**K191184 ImmuView S pneumoniae and L pneumophila Urinary Antigen Test**Mar 5, 2020  
307 days to decisionK191184 · Product code: **MJH** · Microbiology  
Source: <https://www.510kdatabase.net/k191184/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Legionella, Spp., Elisa (MJH)
Date received	May 3, 2019
Decision date	Mar 5, 2020
Days to decision	307 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ssi Diagnostica A/S</b>
Location	Hilleroed, DK
Contact	Pernille Landsbo Elverdal
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bentsen Regulatory and Clinicals Consulting, LLC</b>
Contact	Christopher Bentsen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191184/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 21, 2026