

**K895713 3M IGG FASTLYME(TM) TEST**Dec 14, 1990  
445 days to decisionK895713 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k895713/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Sep 25, 1989
Decision date	Dec 14, 1990
Days to decision	445 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>3M Company</b>
Location	White City, OR, US
Contact	SYLVIA ZORICH
Website	<a href="http://www.3m.com/">http://www.3m.com/</a>
510(k) history	331 submissions · 322 cleared · 1976-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895713/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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