

**K221817 ALFIS Vitamin D, ALFIS-3 Analyzer**Sep 22, 2023  
457 days to decisionK221817 · Product code: **MRG** · Chemistry  
Source: <https://www.510kdatabase.net/k221817/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Vitamin D (MRG)
Date received	Jun 22, 2022
Decision date	Sep 22, 2023
Days to decision	457 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immunostics Inc.,</b>
Location	Ocean, NJ, US
Contact	Young Mi Kim
510(k) history	14 submissions · 14 cleared · 1997-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Boditech Med, Inc.</b>
Contact	Parag Bhurchandi

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221817/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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