FDA 510(k) Premarket Notification

K221817 ALFIS Vitamin D, ALFIS-3 Analyzer

CLEARED

Sep 22, 2023
457 days to decision

K221817 · Product code: **MRG** · Chemistry
Source: https://www.510kdatabase.net/k221817/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Boditech Med, Inc.**
Contact	Parag Bhurchandi

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