FDA 510(k) Premarket Notification

K192064 LIAISON Vitamin B12

CLEARED

Oct 2, 2019
62 days to decision

K192064 · Product code: **CDD** · Chemistry
Source: https://www.510kdatabase.net/k192064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Aug 1, 2019
Decision date	Oct 2, 2019
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**DiaSorin, Inc.**
Location	Ellicott City, MD, US
Contact	John C. Walter
510(k) history	70 submissions · 69 cleared · 1998-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k192064/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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