

**K232587 MAGLUMI 25-OH Vitamin D, MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer**Apr 12, 2024  
231 days to decisionK232587 · Product code: MRG · Chemistry  
Source: <https://www.510kdatabase.net/k232587/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Vitamin D (MRG)
Date received	Aug 25, 2023
Decision date	Apr 12, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shenzhen New Industries Biomedical Engineering Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Xiaoli Wang
510(k) history	5 submissions · 5 cleared · 2017-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>LSI International, Inc.</b>
Contact	Joe Shia

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

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232587/>; Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026