

K213510 IMMULITE/IMMULITE 1000 OM-MA, IMMULITE 2000 OM-MASep 8, 2023
675 days to decisionK213510 · Product code: LTK · Immunology
Source: <https://www.510kdatabase.net/k213510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Nov 2, 2021
Decision date	Sep 8, 2023
Days to decision	675 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics Products, Ltd.
Location	Caerarfon, GB
Contact	Stefani Vinkemeier
510(k) history	4 submissions · 4 cleared · 2021-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213510/>; 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