K213510 IMMULITE/IMMULITE 1000 OM-MA, IMMULITE 2000 OM-MA

CLEARED

Sep 8, 2023
675 days to decision

K213510 · 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