

**K233946 IMMULITE® 2000 BR-MA**Mar 13, 2024  
90 days to decisionK233946 · Product code: **MOI** · Immunology  
Source: <https://www.510kdatabase.net/k233946/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Dec 14, 2023
Decision date	Mar 13, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics Products, Ltd.</b>
Location	Caerarfon, GB
Contact	Karlyn Kellogg
510(k) history	4 submissions · 4 cleared · 2021-2024

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