

**K203270 IMMULITE/IMMULITE® 1000 Cortisol**Jan 15, 2021  
71 days to decisionK203270 · Product code: **CGR** · Chemistry  
Source: <https://www.510kdatabase.net/k203270/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Cortisol (CGR)
Date received	Nov 5, 2020
Decision date	Jan 15, 2021
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203270/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026