

# K250159 Immunoglobulin Isotypes (GAM) for the EXENT Analyser

Oct 17, 2025  
269 days to decision

K250159 · Product code: **SGG** · Immunology  
Source: <https://www.510kdatabase.net/k250159/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mass Spectrometric, Immunoglobulins (g, A, M, D, E) (SGG)
Date received	Jan 21, 2025
Decision date	Oct 17, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EXENT Analyser

## APPLICANT

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Company	<b>The Binding Site Group , Ltd.</b>
Location	Los Angeles, CA, US
Contact	Jolanta Wolff
Website	<a href="http://www.bindingsite.com/">http://www.bindingsite.com/</a>
510(k) history	43 submissions · 43 cleared · 2010-2025

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k250159/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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