

K152875 QUANTA Flash B2GP1-Domain1, QUANTA Flash B2GP1-Domain1 Controls, HemosIL AcuStar Anti-B2GPI Domain 1, HemosIL AcuStar Anti-B2GPI Domain 1 ControlsDec 21, 2015
82 days to decisionK152875 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k152875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Sep 30, 2015
Decision date	Dec 21, 2015
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inova Diagnostics, Inc.
Location	San Diego, CA, US
Contact	GABRIELLA LAKOS
Website	https://www.inovadx.com
510(k) history	138 submissions · 136 cleared · 1988-2026

Siemens Healthcare Diagnostics, Inc. is a leading diagnostic device manufacturer based in New York. The company specializes in laboratory diagnostics and clinical chemistry solutions. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. Chemistry devices and immunology assays represent the core focus of its regulatory portfolio. The latest FDA 510(k) clearance in 2026 reflects continued active development and market engagement. Recent cleared devices include automated chemistry analyzers, immunoassay systems, and special...