

K133582 HEMOSIL D-DIMER HS 500 CONTROLAug 15, 2014
267 days to decisionK133582 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k133582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Nov 21, 2013
Decision date	Aug 15, 2014
Days to decision	267 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Instrumentation Laboratory
Location	Lexington, MA, US
Contact	CAROL MARBLE
510(k) history	3 submissions · 3 cleared · 2008-2023

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