

**K071319 I-STAT ACTIVATED CLOTTING TIME (ACT) CONTROL
SET LEVEL 1 AND LEVEL 2, MODELS 07G82-01, 07G82-02**

Jun 26, 2007
47 days to decision

K071319 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k071319/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	May 10, 2007
Decision date	Jun 26, 2007
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad, Diagnostics Grp.
Location	Irvine, CA, US
Contact	MARIA ZEBALLOS
510(k) history	6 submissions · 6 cleared · 2007-2012

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Device record: <https://www.510kdatabase.net/k071319/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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