

**K884901 DADE(R) PROTOTROL SYNTHETIC SUBSTRATE
ASSAY CONTRO**Feb 2, 1989
71 days to decisionK884901 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k884901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Nov 23, 1988
Decision date	Feb 2, 1989
Days to decision	71 days
Third-party review	No

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	JEANNE-MARIE VARGA
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884901/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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