

K991176 OPUS TROPONIN I CALIBRATORJul 1, 1999
85 days to decisionK991176 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k991176/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Apr 7, 1999
Decision date	Jul 1, 1999
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	REBECCA S AYASH
510(k) history	343 submissions · 343 cleared · 1978-2010

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