

K071811 ETOH FLEX REAGENT CARTRIDGE (DF22)Aug 24, 2007
52 days to decisionK071811 · Product code: **DIC** · Toxicology
Source: <https://www.510kdatabase.net/k071811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method (DIC)
Date received	Jul 3, 2007
Decision date	Aug 24, 2007
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	VICTOR M CARRIO
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071811/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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