

K011852 DIMENSION HAIC ASSAY, MODEL DF105Nov 15, 2001
156 days to decisionK011852 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k011852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 12, 2001
Decision date	Nov 15, 2001
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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