

K073604 DIMENSION EXL WITH LM CLINICAL CHEMISTRY SYSTEM, DIMENSION FT4L FLEX REAGENT CARTRIDGE, AND LOCI THYROID CALIBRATOR, MODMar 13, 2008
83 days to decisionK073604 · Product code: **CEC** · Chemistry
Source: <https://www.510kdatabase.net/k073604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Dec 21, 2007
Decision date	Mar 13, 2008
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k073604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026