

K153538 Dexramer CMV KitMar 2, 2017
448 days to decisionK153538 · Product code: **GKZ** · Immunology
Source: <https://www.510kdatabase.net/k153538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Dec 10, 2015
Decision date	Mar 2, 2017
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Immudex Aps
Location	Copenhagen/Kobenhavn, DK
Contact	Liselotte Brix
510(k) history	1 submissions · 1 cleared · 2017-2017

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