

K120663 MONOCLONAL RABBIT ANTI-HUMAN ESTROGEN RECEPTOR (ER) A, CLONE EPIFeb 12, 2013
344 days to decisionK120663 · Product code: MYA · Pathology
Source: <https://www.510kdatabase.net/k120663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA)
Date received	Mar 5, 2012
Decision date	Feb 12, 2013
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dako North America, Inc.
Location	Carpinteria, CA, US
Contact	XIAOLEI XU
510(k) history	4 submissions · 4 cleared · 2009-2016

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