

K081286 MONOCLONAL RABBIT ANTI HUMAN ESTROGEN RECEPTOR ALPHA ANTIBODY CLONE SP1, MODEL M3634

May 8, 2009
366 days to decision

K081286 · Product code: MYA · Pathology
Source: <https://www.510kdatabase.net/k081286/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA)
Date received	May 7, 2008
Decision date	May 8, 2009
Days to decision	366 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k081286/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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