

K160922 FLEX Monoclonal Rabbitt Anti-Human Estrogen Receptor a, Clone EP1, Ready-to-Use (Link)May 3, 2016
29 days to decisionK160922 · Product code: **MXZ** · Pathology
Source: <https://www.510kdatabase.net/k160922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunohistochemistry Assay, Antibody, Progesterone Receptor (MXZ)
Date received	Apr 4, 2016
Decision date	May 3, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary
Other names	FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 636, Ready-to-Use (Link)

APPLICANT

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

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