

K183100 Estrogen Receptor Clone 6F11 Ready-to-Use Primary Antibody for Bond, Estrogen Receptor Clone 6F11 Liquid Concentrate Primary Antibody, NovocastraDec 7, 2018
30 days to decisionK183100 · Product code: **MYA** · Pathology
Source: <https://www.510kdatabase.net/k183100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA)
Date received	Nov 7, 2018
Decision date	Dec 7, 2018
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Leica Biosystems Newcastle, Limited
Location	Newcastle Upon Tyne, GB
Contact	Jeremy Allen
510(k) history	3 submissions · 3 cleared · 2017-2018

REGULATORY CONSULTANT

Consulting firm	Leica Biosystems, Inc.
Contact	Zhijun (Julie) Pan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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