

**K183102 BOND Ready-to-Use (RTU) Primary Antibody Progesterone Receptor (16) , Novocastra Concentrated Liquid Mouse Monoclonal Antibody**Dec 7, 2018  
30 days to decisionK183102 · Product code: **MXZ** · Pathology  
Source: <https://www.510kdatabase.net/k183102/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunohistochemistry Assay, Antibody, Progesterone Receptor (MXZ)
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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Leica Biosystems, Inc.</b>
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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