

K193393 BOND Ready-to-Use Primary Antibody Progesterone Receptor (16), Novocastra Liquid Mouse Monoclonal Antibody Progesterone Receptor Clone 16 (Concentrated Liquid Antibody Format).Mar 6, 2020
91 days to decisionK193393 · Product code: **MXZ** · Pathology
Source: <https://www.510kdatabase.net/k193393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemistry Assay, Antibody, Progesterone Receptor (MXZ)
Date received	Dec 6, 2019
Decision date	Mar 6, 2020
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Leica Biosystems Newcastle, Ltd.
Location	Richmond, IL, US
Contact	Matthew West
Website	http://www.leicabiosystems.com/
510(k) history	3 submissions · 3 cleared · 2014-2023

Leica Biosystems Newcastle, Ltd. specializes in anatomical pathology equipment and workflow solutions. The company operates with a manufacturing facility in Richmond, US. Their mission centers on advancing cancer diagnostics and improving lives through integrated histology, immunohistochemistry, and digital pathology technologies. The company has received FDA 510(k) clearances from total submissions. All submissions focused on Pathology devices. Clearances span from 2014 to 2023, with notable products including antibody panels and immunohistochemistry reagents. The compan...

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