

**K122556 VISION BIOSYSTEMS ESTROGEN RECEPTOR CLONE
6F11 (ER 6F11)**May 19, 2014
635 days to decisionK122556 · Product code: MYA · Pathology
Source: <https://www.510kdatabase.net/k122556/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA)
Date received	Aug 22, 2012
Decision date	May 19, 2014
Days to decision	635 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Leica Biosystems Newcastle, Ltd.
Location	Richmond, IL, US
Contact	BARBARA-ANN CONWAY-MAYERS
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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