

K213348 BOND MMR Antibody PanelFeb 21, 2023
501 days to decisionK213348 · Product code: **PZJ** · Pathology
Source: <https://www.510kdatabase.net/k213348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lynch Syndrome Test System (PZJ)
Date received	Oct 8, 2021
Decision date	Feb 21, 2023
Days to decision	501 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Leica Biosystems Newcastle, Ltd.
Location	Richmond, IL, US
Contact	Kristin Godfredsen
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...