

K172078 ImmuLisa Enhanced RNA POL III Antibody ELISAMar 30, 2018
263 days to decisionK172078 · Product code: **NYO** · Immunology
Source: <https://www.510kdatabase.net/k172078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Anti-ribonucleic Acid Polymerase (rnap) Iii Antibody (NYO)
Date received	Jul 10, 2017
Decision date	Mar 30, 2018
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Immco Diagnostics, Inc.
Location	Buffalo, NY, US
Contact	Kevin Lawson
510(k) history	55 submissions · 55 cleared · 1988-2018

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