

K172745 ImmuGlo HEp-2 Elite IFAJun 5, 2018
266 days to decisionK172745 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k172745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Sep 12, 2017
Decision date	Jun 5, 2018
Days to decision	266 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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