

K131791 IFA 40: HEP-20-10Feb 26, 2014
253 days to decisionK131791 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k131791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Jun 18, 2013
Decision date	Feb 26, 2014
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Euroimmun US
Location	Morris Plains, NJ, US
Contact	MICHAEL LOCKE
510(k) history	12 submissions · 11 cleared · 2012-2016

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