

K141827 EUROIMMUN IFA 40: HEP-20-10Apr 17, 2015
284 days to decisionK141827 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k141827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Jul 7, 2014
Decision date	Apr 17, 2015
Days to decision	284 days
Third-party review	No
Summary / Statement	Statement
Other names	EUROPATTERN MICROSCOPE AND SOFTWARE

APPLICANT

Company	Euroimmun Us, Inc.
Location	Morristown, NJ, US
Contact	MICHAEL A LOCKE
510(k) history	19 submissions · 19 cleared · 2009-2020

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