

K172252 EUROIMMUN IFA: Crithidia luciliae sensitive (anti-dsDNA) EUROPatternApr 20, 2018
268 days to decisionK172252 · Product code: KTL · Immunology
Source: <https://www.510kdatabase.net/k172252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Indirect Immunofluorescent Solid Phase (KTL)
Date received	Jul 26, 2017
Decision date	Apr 20, 2018
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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