K193115 EUROIMMUN Anti-BP230-CF ELISA (IgG)

CLEARED

Sep 17, 2020
310 days to decision

K193115 · Product code: **OEG** · Immunology
Source: https://www.510kdatabase.net/k193115/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Skin (bullous Pemphigoid 180 And Bullous Pemphigoid 230 (OEG)
Date received	Nov 12, 2019
Decision date	Sep 17, 2020
Days to decision	310 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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