

K193115 EUROIMMUN Anti-BP230-CF ELISA (IgG)Sep 17, 2020
310 days to decisionK193115 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193115/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026