FDA 510(k) Premarket Notification

CLEARED

K113020 IMMULISA ENHANCED (TM) CARDIOLIPIN IGA, IGG, IGM AND IGA/IGG/IGM ANTIBODY (ACA) ELISAS

Oct 25, 2012
380 days to decision

K113020 · Product code: **MID** · Immunology
Source: https://www.510kdatabase.net/k113020/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Oct 11, 2011
Decision date	Oct 25, 2012
Days to decision	380 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Immco Diagnostics, Inc.**
Location	Buffalo, NY, US
Contact	KEVIN J LAWSON
510(k) history	55 submissions · 55 cleared · 1988-2018

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k113020/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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