

**K192727 K-ASSAY (R) RF (Ver.2), K-ASSAY (R) RF Calibrator
(Ver.2)**May 20, 2020
236 days to decisionK192727 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k192727/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Sep 27, 2019
Decision date	May 20, 2020
Days to decision	236 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Kamiya Biomedical Company
Location	Tukwila, WA, US
Contact	Shawn Kaplan
510(k) history	2 submissions · 2 cleared · 2012-2020

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