FDA 510(k) Premarket Notification

CLEARED

K193613 Allergen-Specific IgE Assay 12 Allergen Bundle

Oct 18, 2021
662 days to decision

K193613 · Product code: **DHB** · Immunology
Source: https://www.510kdatabase.net/k193613/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Dec 26, 2019
Decision date	Oct 18, 2021
Days to decision	662 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Hitachi Chemical Diagnostics, Inc.**
Location	Mountain View, CA, US
Contact	Christina Kong
510(k) history	16 submissions · 16 cleared · 2003-2021

REGULATORY CONSULTANT

Consulting firm	**Minaris Medical**
Contact	Erika Ammirati

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov