FDA 510(k) Premarket Notification

CLEARED

K201256 Procise CRP, ProciseDx Analyzer, ProciseDx Calibration Cartridge

Nov 4, 2022
907 days to decision

K201256 · Product code: **DCK** · Immunology
Source: https://www.510kdatabase.net/k201256/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	May 11, 2020
Decision date	Nov 4, 2022
Days to decision	907 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Procise Diagnostics**
Location	San Diego, CA, US
Contact	Dan Kiser
510(k) history	1 submissions · 1 cleared · 2022-2022