K212779 Coag-Sense Prothrombin (PT) / INR Monitoring System for Patient Self-Testing

CLEARED

Oct 5, 2022
399 days to decision

K212779 · Product code: **GJS** · Hematology
Source: https://www.510kdatabase.net/k212779/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Time, Prothrombin (GJS)
Date received	Sep 1, 2021
Decision date	Oct 5, 2022
Days to decision	399 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Coagusense, Inc.**
Location	Fremont, CA, US
Contact	Michael Acosta
510(k) history	3 submissions · 3 cleared · 2010-2022