FDA 510(k) Premarket Notification

K203771 Urea Nitrogen2

CLEARED

May 31, 2022
524 days to decision

K203771 · Product code: **CDQ** · Chemistry
Source: https://www.510kdatabase.net/k203771/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Dec 23, 2020
Decision date	May 31, 2022
Days to decision	524 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Ireland Diagnostics Division**
Location	Longford, IE
Contact	Tiffini Jenkins
510(k) history	8 submissions · 8 cleared · 2021-2023