

**K203248 Albumin BCG2**Nov 23, 2021  
384 days to decisionK203248 · Product code: **CIX** · Chemistry  
Source: <https://www.510kdatabase.net/k203248/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromocresol Green Dye-binding, Albumin (CIX)
Date received	Nov 4, 2020
Decision date	Nov 23, 2021
Days to decision	384 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Abbott Ireland Diagnostics Division</b>
Location	Longford, IE
Contact	Suzanne Cheang
510(k) history	8 submissions · 8 cleared · 2021-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203248/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026