

**K861467 ALBUMIN (BCG) REAGENT**May 23, 1986  
32 days to decisionK861467 · Product code: **CIX** · Chemistry  
Source: <https://www.510kdatabase.net/k861467/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromcresol Green Dye-binding, Albumin (CIX)
Date received	Apr 21, 1986
Decision date	May 23, 1986
Days to decision	32 days
Third-party review	No

**APPLICANT**

---

Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	MATHEW MADAPPALLY
510(k) history	164 submissions · 164 cleared · 1984-2002

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861467/>; 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 14, 2026