

**K891544 DIALBUMIN**Jun 9, 1989  
84 days to decisionK891544 · Product code: **JIR** · Chemistry  
Source: <https://www.510kdatabase.net/k891544/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator Method, Protein Or Albumin (urinary, Non-quant.) (JIR)
Date received	Mar 17, 1989
Decision date	Jun 9, 1989
Days to decision	84 days
Third-party review	No

**APPLICANT**

---

Company	<b>Exocell, Inc.</b>
Location	Philadelphia, PA, US
Contact	COHEN, M.D.
510(k) history	5 submissions · 5 cleared · 1989-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891544/>; 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 June 30, 2026