

**K843225 COLORZYME NDNA TEST SYSTEM**Nov 1, 1984  
77 days to decisionK843225 · Product code: **DHN** · Immunology  
Source: <https://www.510kdatabase.net/k843225/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Aug 16, 1984
Decision date	Nov 1, 1984
Days to decision	77 days
Third-party review	No

**APPLICANT**

---

Company	<b>Immuno Concepts, Inc.</b>
Location	Mchenry, IL, US
Contact	DON W VALENCIA
510(k) history	36 submissions · 36 cleared · 1981-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k843225/> 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 29, 2026