

**K950979 HEP-2000 COLORZYME ANA-RO TEST SYSTEM**

Jun 1, 1995  
90 days to decision

K950979 · Product code: **DHN** · Immunology  
Source: <https://www.510kdatabase.net/k950979/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Mar 3, 1995
Decision date	Jun 1, 1995
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k950979/> 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