

**K944096 HEP-2000 FLUORESCENT ANA-RO TEST SYSTEM**Nov 21, 1994  
91 days to decisionK944096 · Product code: **DHN** · Microbiology  
Source: <https://www.510kdatabase.net/k944096/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Aug 22, 1994
Decision date	Nov 21, 1994
Days to decision	91 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/k944096/> 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