

**K001556 HEP-2 ANA TEST SYSTEM WITH IF-AIM
TECHNOLOGY**Aug 21, 2000
95 days to decisionK001556 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k001556/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN) |
| Date received | May 18, 2000 |
| Decision date | Aug 21, 2000 |
| Days to decision | 95 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | The Binding Site, Ltd. |
| Location | Los Angeles, CA, US |
| Contact | JAY H GELLER |
| 510(k) history | 115 submissions · 115 cleared · 1988-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001556/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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