

K860428 SM-RNP AUTOANTIBODY TEST SYSTEMMay 15, 1986
100 days to decisionK860428 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k860428/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Extractable Antinuclear Antibody, Antigen And Control (LLL) |
| Date received | Feb 4, 1986 |
| Decision date | May 15, 1986 |
| Days to decision | 100 days |
| Third-party review | No |

APPLICANT

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

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