

K760681 INDIRECT FLUORESCENT (IFA-ANA)Oct 21, 1976
31 days to decisionK760681 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k760681/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN) |
| Date received | Sep 20, 1976 |
| Decision date | Oct 21, 1976 |
| Days to decision | 31 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Wampole Laboratories |
| Location | Mchenry, IL, US |
| 510(k) history | 12 submissions · 12 cleared · 1976-1997 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k760681/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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