

**K872845 BION ANTINUCLEAR ANTIBODY(ANA)TEST
KIT/CONTR SERUM**Aug 17, 1987
28 days to decisionK872845 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k872845/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN) |
| Date received | Jul 20, 1987 |
| Decision date | Aug 17, 1987 |
| Days to decision | 28 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Bion Ent., Ltd. |
| Location | Mchenry, IL, US |
| Contact | EDWARD NOWAKOWSKI |
| 510(k) history | 14 submissions · 14 cleared · 1980-1993 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k872845/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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