

K905386 DISTAT ANTI-DSDNA KITDec 13, 1990
13 days to decisionK905386 · Product code: **KTL** · Immunology
Source: <https://www.510kdatabase.net/k905386/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Anti-dna Indirect Immunofluorescent Solid Phase (KTL) |
| Date received | Nov 30, 1990 |
| Decision date | Dec 13, 1990 |
| Days to decision | 13 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Shield Diagnostics, Ltd. |
| Location | Scotland, KN |
| Contact | GEORGE ZAJICEK |
| 510(k) history | 27 submissions · 27 cleared · 1990-2000 |

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