

K953686 HELISAL RAPID BLOOD TESTMay 21, 1996
295 days to decisionK953686 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k953686/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Helicobacter Pylori (LYR) |
| Date received | Jul 31, 1995 |
| Decision date | May 21, 1996 |
| Days to decision | 295 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cortecs, Ltd. |
| Location | West Cadwell, NJ, US |
| Contact | ROBERT SCHIFF |
| 510(k) history | 1 submissions · 1 cleared · 1996-1996 |

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