

K883148 IMMUKNOW-CHECK HCG ASSAY KIT, CAT. #900-40Dec 5, 1988
132 days to decisionK883148 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k883148/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Human Chorionic Gonadotropin (DHA) |
| Date received | Jul 26, 1988 |
| Decision date | Dec 5, 1988 |
| Days to decision | 132 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Chemicals, Ltd. (Usa) |
| Location | Walker, MI, US |
| Contact | REGIS DUFFY |
| 510(k) history | 77 submissions · 76 cleared · 1984-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883148/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026