

K812658 CEA CONTROL PLASMASep 29, 1981
11 days to decisionK812658 · Product code: **DHX** · Immunology
Source: <https://www.510kdatabase.net/k812658/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Carcinoembryonic Antigen (DHX) |
| Date received | Sep 18, 1981 |
| Decision date | Sep 29, 1981 |
| Days to decision | 11 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Pacific Hemostasis |
| Location | Mchenry, IL, US |
| 510(k) history | 29 submissions · 29 cleared · 1978-2000 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k812658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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