

K822124 TITAN GEL CPK ISOENZYME SYSTEMNov 1, 1982
105 days to decisionK822124 · Product code: **JHT** · Chemistry
Source: <https://www.510kdatabase.net/k822124/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Chromatographic Separation, Cpk Isoenzymes (JHT) |
| Date received | Jul 19, 1982 |
| Decision date | Nov 1, 1982 |
| Days to decision | 105 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Helena Laboratories |
| Location | Mchenry, IL, US |
| 510(k) history | 280 submissions · 280 cleared · 1978-2013 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k822124/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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