

**K914946 CASCADE 480(TM) AUTO COAG ANALYZER,
MODIFICATION**Jan 13, 1992
76 days to decisionK914946 · Product code: **GKP** · Hematology
Source: <https://www.510kdatabase.net/k914946/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Coagulation, Automated (GKP) |
| Date received | Oct 29, 1991 |
| Decision date | Jan 13, 1992 |
| Days to decision | 76 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914946/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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