

**K981174 CRYO CHECK FACTOR XII DEFICIENT PLASMA
MODEL FDP12-10 (1.0ML) AND FDP12-15 (1.5ML)**

Jan 13, 1999
287 days to decision

K981174 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k981174/>

SUBMISSION DETAILS

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plasma, Coagulation Factor Deficient (GJT) |
| Date received | Apr 1, 1998 |
| Decision date | Jan 13, 1999 |
| Days to decision | 287 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Precision Biologicals, Inc. |
| Location | Dartmouth, CA |
| Contact | SANDY MORRISON |
| 510(k) history | 20 submissions · 20 cleared · 1989-1999 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k981174/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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