

**K961814 THROMBOLYTIC ASSESSMENT SYSTEM  
PROTHROMBIN TIME TEST CONTROLS**Aug 13, 1996  
95 days to decisionK961814 · Product code: **GIZ** · Hematology  
Source: <https://www.510kdatabase.net/k961814/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Plasma, Control, Normal (GIZ)      |
| Date received         | May 10, 1996                       |
| Decision date         | Aug 13, 1996                       |
| Days to decision      | 95 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cardiovascular Diagnostics, Inc.</b> |
| Location       | Raleigh, NC, US                         |
| Contact        | James M Clinton                         |
| 510(k) history | 13 submissions · 13 cleared · 1995-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961814/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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