

K012371 TINA-QUANT TRANSFERRIN VER.2Sep 19, 2001
55 days to decisionK012371 · Product code: **DDG** · Immunology
Source: <https://www.510kdatabase.net/k012371/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transferrin, Antigen, Antiserum, Control (DDG) |
| Date received | Jul 26, 2001 |
| Decision date | Sep 19, 2001 |
| Days to decision | 55 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------|
| Company | Roche Diagnostics Corp. |
| Location | Indianapolis, IN, US |
| Contact | SHERRI L COENEN |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

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