

K013207 TINA-QUANT APOLIPOPROTEIN B VER.2Nov 13, 2001
49 days to decisionK013207 · Product code: **DFC** · Chemistry
Source: <https://www.510kdatabase.net/k013207/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC) |
| Date received | Sep 25, 2001 |
| Decision date | Nov 13, 2001 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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