

K182095 Tina-quant Transferrin ver.2 (urine application)Nov 5, 2018
94 days to decisionK182095 · Product code: **DDG** · Immunology
Source: <https://www.510kdatabase.net/k182095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transferrin, Antigen, Antiserum, Control (DDG)
Date received	Aug 3, 2018
Decision date	Nov 5, 2018
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations (Rdo)
Location	Indianapolis, IN, US
Contact	Lindsay Jones
510(k) history	14 submissions · 14 cleared · 2014-2020

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