FDA 510(k) Premarket Notification

K100538 TINA-QUANT FERRITIN GEN. 4

CLEARED

Jun 22, 2010
117 days to decision

K100538 · Product code: **DBF** · Immunology
Source: https://www.510kdatabase.net/k100538/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ferritin, Antigen, Antiserum, Control (DBF)
Date received	Feb 25, 2010
Decision date	Jun 22, 2010
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics**
Location	Indianapolos, IN, US
Contact	KATHIE J GOODWIN
Website	https://diagnostics.roche.com
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...