FDA 510(k) Premarket Notification

CLEARED

K153301 Elecsys Digoxin Immunoassay, Elecsys PreciControl Cardiac II

Apr 8, 2016
147 days to decision

K153301 · Product code: **KXT** · Chemistry
Source: https://www.510kdatabase.net/k153301/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Nov 13, 2015
Decision date	Apr 8, 2016
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics**
Location	Indianapolos, IN, US
Contact	EDIE EADS
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...