

K162895 Elecsys Troponin T Gen 5 STAT Assay, Elecsys Troponin T Gen 5 STAT CalSet, Elecsys PreciControl Troponin, Elecsys Troponin T Gen 5 CalCheck 5Jan 18, 2017
93 days to decisionK162895 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k162895/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Oct 17, 2016
Decision date	Jan 18, 2017
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	Jane Phillips
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...