

K153607 ROMA Calculation Tool Using Elecsys AssaysJun 15, 2016
181 days to decisionK153607 · Product code: **ONX** · Immunology
Source: <https://www.510kdatabase.net/k153607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ovarian Adnexal Mass Assessment Score Test System (ONX)
Date received	Dec 17, 2015
Decision date	Jun 15, 2016
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	Angelo Pereira
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...
