

K081193 COBAS INTEGRA 400/800 BILIRUBIN TOTALJan 16, 2009
263 days to decisionK081193 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k081193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Apr 28, 2008
Decision date	Jan 16, 2009
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	JENNIFER TRIBBETT
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...
