FDA 510(k) Premarket Notification

K192815 Elecsys BRAHMS PCT

CLEARED

Mar 9, 2020
160 days to decision

K192815 · Product code: **PRI** · Microbiology
Source: https://www.510kdatabase.net/k192815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Procalcitonin Assay (PRI)
Date received	Oct 1, 2019
Decision date	Mar 9, 2020
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics**
Location	Indianapolis, IN, US
Contact	Wes Gerbig
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...