FDA 510(k) Premarket Notification

CLEARED

K003120 MODIFICATION TO INTEGRA REAGENT CASSETTE FOR HEMOGLOBIN A1C

Dec 18, 2000
74 days to decision

K003120 · Product code: **LCP** · Hematology
Source: https://www.510kdatabase.net/k003120/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 5, 2000
Decision date	Dec 18, 2000
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics Corp.**
Location	Indianapolis, IN, US
Contact	KAY A TAYLOR
510(k) history	264 submissions · 263 cleared · 1999-2013