FDA 510(k) Premarket Notification

K190405 BACT/ALERT MP Reagent System

CLEARED

May 15, 2019
85 days to decision

K190405 · Product code: **MDB** · Microbiology
Source: https://www.510kdatabase.net/k190405/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Blood Culturing (MDB)
Date received	Feb 19, 2019
Decision date	May 15, 2019
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**bioMerieux, Inc.**
Location	Mchenry, IL, US
Contact	Esther Hernandez
510(k) history	251 submissions · 250 cleared · 1983-2026