FDA 510(k) Premarket Notification

CLEARED

K162395 MP DOA-10 Panel Test Cup, MP DOA-11 Panel Test Cup

Jun 2, 2017
280 days to decision

K162395 · Product code: **DIO** · Toxicology
Source: https://www.510kdatabase.net/k162395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Aug 26, 2016
Decision date	Jun 2, 2017
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mp Biomedicals, LLC**
Location	Northridge, CA, US
Contact	STAR HAN
510(k) history	2 submissions · 2 cleared · 2006-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k162395/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026