FDA 510(k) Premarket Notification

K093116 MODIFICATION TO: RAMP INFLUENZA A/B ASSAY

CLEARED

Oct 21, 2009
19 days to decision

K093116 · Product code: **PSZ** · Microbiology
Source: https://www.510kdatabase.net/k093116/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Oct 2, 2009
Decision date	Oct 21, 2009
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Response Biomedical Corp.**
Location	Burnaby, British Columbia, CA
Contact	KEN PILGRIM
510(k) history	7 submissions · 7 cleared · 2001-2009