FDA 510(k) Premarket Notification

CLEARED

K182513 FluChip-8G Influenza A+B Assay

Apr 22, 2019
222 days to decision

K182513 · Product code: **OZE** · Microbiology
Source: https://www.510kdatabase.net/k182513/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Sep 12, 2018
Decision date	Apr 22, 2019
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Indevr, Inc.**
Location	Boulder, CO, US
Contact	Erica Dawson
Website	http://www.indevr.com/
510(k) history	1 submissions · 1 cleared · 2019-2019

Indevr, Inc. is a global leader in analytical technologies for vaccine development and manufacturing. Now part of SSI Diagnostica A/S, the company operates from Boulder, Colorado and specializes in multiplexed immunoassay solutions and automated hemagglutination analysis systems. Indevr has received FDA 510(k) clearance from total submission. The company's regulatory focus centers on Microbiology devices, with its first and only clearance granted in 2019. The cleared device, FluChip-8G Influenza A+B Assay, reflects the company's core expertise in rapid viral diagnostics. ...