DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K181443

Device Name

Accula RSV Test

Indications for Use *(Describe)*

The Accula RSV Test performed on the Accula Dock is a molecular *in vitro* diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of respiratory syncytial virus (RSV) viral RNA. The Accula RSV Test uses a nasal swab specimen collected from patients with signs and symptoms of respiratory infection. The Accula RSV assay is intended as an aid in the diagnosis of RSV infection in children and adults in conjunction with clinical and epidemiological risk factors.

Negative results do not preclude RSV virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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