

## Indications for Use

510(k) Number (if known)

K210086

Device Name

Vitals360® Multi-Vitals Mobile Monitor

Indications for Use (Describe)

Vitals360® device is intended to be used for measuring, displaying, reviewing and storing of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), forehead temperature (TEMP), ECG, weight and height in adults no less than 18 years of age.

This VITALS360® device is intended for use by trained adults only who can use smartphones proficiently.

This VITALS360® device is intended for use in a clinical or home environment.

This VITALS360® device is a reusable device following thorough cleaning between uses.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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