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)*

K181832

Device Name
Welch Allyn 901123 Digital Blood Pressure Device ProBP 2000

Indications for Use *(Describe)*

The Welch Allyn ProBP 2000 Digital blood pressure device is intended for use in measuring blood pressure and heart rate in patients at least 3 years of age or older with arm circumferences between 15 cm to 55 cm (approximately 5.9 to 21.7 inches).

The Welch Allyn ProBP 2000 automatically measures systolic and diastolic pressure and pulse rate. The device is intended to be used by clinicians and medically qualified personnel.

Contraindications:
This device is not intended for use on neonates, infants, or children under the age of 3 years. The effectiveness of this device has not been established in pregnant, including pre-eclamptic, patients.

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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