

Indications for Use

510(k) Number (if known)

Device Name

{填写申报产品名称 }

(参考示例: Portable ECG Monitor (ECG3))

Indications for Use (Describe)

{填写申报产品预期用途}

(参考示例:

The ECG3 is intended for use in a community hospital or at home and it is a dynamic electrocardiogram measurement system. It is designed to measure and record ECG data of an adult individual in the long term by using a technique in which an electrode was pasted on the chest.

The ECG3 Portable ECG Monitor is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.)

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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