

16. 510(k) SUMMARY

K960468

January 31, 1996

APR 26 1996

1. COMPANY INFORMATION

Establishment: Puritan-Bennett Corp.
9728 Pflumm Road
Lenexa, KS 66285-5915

Official Correspondent: C. Marshall Smith
Project Manager, Regulatory Affairs

2. KIT NAME

Proprietary: DMR/CO2 Combo Kit

Common/Usual: Disposable Manual Resuscitator and CO2
Detector

Classification: Kit unclassified

3. EQUIVALENT DEVICE

The *DMR/CO2 Combo Kit* is comprised of the following devices:

- *Nellcor Puritan Bennett* Disposable Manual Resuscitator (DMR) K943617; and either
- *Nellcor Puritan Bennett* Easy Cap End-Tidal CO2 Detector K894053, or
- *Nellcor Puritan Bennett* Pedi-Cap Pediatric End-Tidal CO2 Detector - K944400

These devices have been found to be substantially equivalent through the premarket notification process.

4. DEVICE DESCRIPTION

The *DMR/CO2 Combo Kit* is comprised of the following devices:

Nellcor Puritan Bennett Disposable Manual Resuscitator (DMR) is a bag-valve-mask device with the capability of delivering supplemental oxygen. During artificial ventilation, the resuscitator can be operated from ambient air or provide oxygen-enriched air by extending the oxygen accumulator and connecting supply tubing to a metered oxygen source. It is a non-sterile, single-patient use device.

Nellcor Puritan Bennett Easy Cap Detector, when connected between an endotracheal tube and a breathing device, detects approximate ranges of end-tidal CO₂ by color comparison in patients weighing more than 15 kg (33 lbs.). The detector may be used during patient transport or in any location where intubations are performed. It may be used for up to two hours. The *Easy Cap* detector assists verification of tube placement during endotracheal or nasotracheal intubation. It may be used on intubated patients to detect approximate ranges of end-tidal CO₂ when clinically significant.

Nellcor Puritan Bennett Pedi-Cap Pediatric End-Tidal CO₂ Detector detects approximate ranges of end-tidal CO₂ by color comparison in patients weighing 1 to 15 kg (2.2 to 33 lbs.). It is intended for use during endotracheal or nasotracheal intubation to assist verification of tube placement. It is also intended for use on intubated patients where measuring approximate ranges of end-tidal CO₂ may be clinically significant and other more precise methods are not feasible or available, i.e., during cardiac arrest or respiratory insufficiency. The *Pedi-Cap* detector connects to an endotracheal tube and a breathing device. It may be used during patient transport or in any location where intubations are performed. It is a non-sterile, disposable, single use end-tidal CO₂ detector which may be used for up to two hours.

5. INTENDED USE

The inclusion of the following components in the *DMR/CO₂ Combo Kit* does not alter the intended use of the individual components in any way.

The *Disposable Manual Resuscitator (DMR)* is a bag-valve-mask device with the capability of delivering supplemental oxygen. During artificial ventilation, the resuscitator can be operated from ambient air or provide oxygen-enriched air by extending the oxygen accumulator and connecting supply tubing to a metered oxygen source.

The *Easy Cap* detector, when connected between an endotracheal tube and a breathing device, detects approximate ranges of end-tidal CO₂ by color comparison in patients weighing more than 15 kg (33 lbs.). The detector may be used during patient transport or in any location where intubations are performed. It may be used for up to two hours. The *Easy Cap* detector assists verification of tube placement during endotracheal or nasotracheal intubation. It may be used on intubated patients to detect approximate ranges of end-tidal CO₂ when clinically significant.

The *Pedi-Cap* detector detects approximate ranges of end-tidal CO₂ by color comparison. It is intended for use during endotracheal or nasotracheal intubation to assist verification of tube placement. It is also intended for use on intubated patients where measuring approximate ranges of end-tidal CO₂ may be clinically significant and other more precise methods are not feasible or available, i.e., during cardiac arrest or respiratory insufficiency. The *Pedi-Cap* detector connects to an endotracheal tube and a breathing device.