

 INTERNATIONAL SAFETY INC.

K955520

510(K) SUMMARY

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Device name:

Proprietary name: Rescue Breather™
Common or usual name: Cardiopulmonary Resuscitation (CPR) mask.
Classification name: Nonbreathing valve, Class II, 21 CFR 868.5870.

Legally marketed device for substantial equivalence comparison:
Res-Cue Key™ and Life Key™ by Ambu, Inc. cleared under K900260.

Description of the device:

The device is a flat sheet measuring 6" by 11" which has integral ear loops to hold it in position during use. The mask provides separation between the skin, mucous membranes and oral secretions of the patient and the rescuer. There is a one-way valve in the middle of the mask which directs breathing flow to the patient.

Intended Use of Device:

The Rescue Breather is intended to separate the patient and the rescuer during cardiopulmonary resuscitation (CPR) on adults and children. It is a single use device and is not sold sterile. The intended use of the Res-Cue Key/Life Key is identical.

Technological Characteristics:

The Rescue Breather and the Res-Cue Key/Life Key are both sheet-type masks with ear loops for attachment to the patient. Both have one-way valves in the middle of the mask. Neither device has any portion which extends into the patient's mouth. The two devices are composed of different materials. The Rescue Breather is composed of surgical glove quality natural latex and nylon. The Res-Cue Key and Life Key are composed of high and low density polymers.

Performance Data

Testing delineated in the ASTM Standard F 920-93 has been conducted. The device meets all specifications relevant to its features.