

JUN 10 1996

K955634

SMDA Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Product: Montgomery Tracheostomy Speaking Valve (15mm / 22mm)

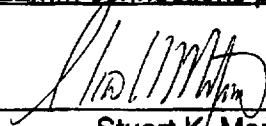
Description: Montgomery® Tracheostomy Speaking Valves are designed to offer ventilator dependent patients the opportunity to speak without having to wait for the ventilator to cycle, allowing patients to speak during inspiration and expiration without interruption. The valve is placed in-line between the tracheostomy tube and the ventilator and features a thin silicone diaphragm which opens on inspiration and closes on expiration.

Indications For Use: For use as a one-way speaking valve between a tracheostomy tube and ventilation equipment.

Predicate Device: Tracheostomy Speaking Valve (15mm / 22mm), Product No. 007 marketed by Passy and Passy (4521 Campus Drive, Irvine, CA).

Testing: Each valve is visually inspected for defects and tested with ISO 5356-1 test gauges for 15mm and 22mm connections prior to packaging.

Submitted by:

 PRESIDENT
Stuart K. Montgomery, President

Date: April 9, 1996