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SECTION 2 - SUMMARY AND CERTIFICATION

510(k) SUMMARY

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Device Proprietary Name: TruPeak Peak Flow Meter
Device Classification name: Peak Flow Meter for
Spirometry, 73 BZH

Legally Marketed Device Identity: TruZone Peak Flow
Meter, 510(k) #926307

Device Description:

The TruPeak Peak Flow Meter is a simple mechanical device that responds to and indicates the Peak Expiratory Flow Rate (PEFR) generated by the user during a forced exhalation maneuver.

The inlet of the device is placed into the user's mouth after which the maximum rate at exhalation is attempted from nearly full lungs. As this forced exhalation commences an internal piston extends a spring as reaction to an internal pressure spike. An indicator is pushed by the moving piston and remains at the maximum displacement position of the piston after the maneuver is terminated. This position corresponds to the PEFR and is quantified in liters per minute by reading a scale next to the indicator. The piston displacement function is logarithmic thereby providing greater resolution of scale at lower PEFR readings.

The TruPeak Peak Flow Meter is identical in form and function to the TruZone Peak Flow Meter as described in its 510(k) #926307 except for the use of zone management tapes. The essence of the modification to this 510(k) is changes in the device labeling to conform to the "Guidance for labeling Peak Flow Meters for Over the Counter Sale", dated June 1993.