

K964130

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SECTION 2 - SUMMARY AND CERTIFICATION

510(k) SUMMARY

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Date Prepared: October 1, 1996

Device Proprietary Name: AeroGear Asthma Action Kit
Device Classification name: Unknown

Legally Marketed Device Identity:

AeroChamber w/FLOWSIGNAL, 510(k) #872037/A
TruZone Peak Flow Meter, 510(k) #926307

Device Description:

The AeroGear Asthma Action Kit is a product containing the AeroChamber Aerosol Holding Chamber, TruZone Peak Flow Meter, a fanny pack and educational materials used in an asthma management program. This kit is intended to be marketed to hospitals, outpatient clinics and physicians.

The two devices indicated above are currently marketed devices which have been cleared through the 510(k) process.