

K 95656

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS :

The North State Plastics Aerosol Tee has been found to be substantially equivalent to currently marketed devices (e.g. Hudson, Baxter, B & B, and Marquest).

Like the predicate devices, the North State Plastics Aerosol Tee is intended for use in providing a conduit for aerosol medications and respiratory gases. The North State Plastics device performs the same function as alternative referenced devices.

The device is injection molded from clear, rigid, clean, chemically inert K-Resin KRO3-NW. The Aerosol Tee is equipped with standard 18 and 22 mm OD fittings for connection to most aerosol devices. Competitively marketed devices utilize essentially the same component materials.

The North State Plastics Aerosol Tee is simplistic in design and easily used in multiple respiratory aerosol configurations.