

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS :

The North State Plastics Respiratory Mouthpiece has been found to be substantially equivalent to currently marketed devices (e.g. Hudson, Baxter, Marquest, Pari, Precision, and Salter).

Like the predicate devices, the North State Plastics Respiratory Mouthpiece is intended for use in providing a direct source of continuous aerosol medication. The North State Plastics device performs the same function as alternative referenced devices.

The device is injection molded from rigid, clean, chemically inert High Density Polyethylene. The Mouthpiece is equipped with a standard 22mm OD fitting for connection to most aerosol devices. Competitively marketed devices utilize essentially the same component materials.

The North State Plastics Respiratory Mouthpiece is simplistic in design and easily used in multiple respiratory applications.