Food and Drug Administration, HHS

§ 874.3375 Battery-powered artificial larynx.

(a) Identification. A battery-powered artificial larynx is an externally applied device intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voicebox, the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in