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510(k) Notification Summary-
Myerson Economy Denture Base Material

Myerson Economy Denture Base Material is intended for use in the fabrication of full and partial dentures.

The Myerson Economy Denture Base Material is a conventional dough pack heat cure denture base material that consists of a polymethyl methacrylate polymer powder with a heat cure monomer consisting of methyl methacrylate, crosslinker (either EGDMA or TEGDMA), 0-1% UV Light Absorber.

The polymer is shaded to simulate the color of gum tissue using pigments that appear on the FDA list of approved products.

This product is substantially equivalent to predicate denture base systems currently on the market which are either pre-amendment devices marketed via 510(K) notification.

The safety and effectiveness of these systems are well documented in the dental literature and the subject products have been formulated to comply with the applicable American Dental Association Standards for denture base materials and relines and repair denture base materials.