

3 Summary of Data and Information [814.20(b)(3)]

3.1 Indications for Use [814.20(b)(3)(i)]

Restylane[®] is indicated for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. Medicis proposes to amend the product's indication to include lip augmentation.

3.2 Device Description [814.20(b)(3)(ii)]

Restylane[®] is a gel of hyaluronic acid generated by *Streptococcus* species of bacteria, chemically crosslinked with BDDE, stabilized and suspended in phosphate buffered saline at pH = 7 and concentration of 20 mg/mL. *Restylane* is a transparent, viscous, and sterile gel that is supplied in a disposable glass syringe. The product is approved in fill sizes containing 0.4, 0.7, 1, or 2 mL of gel. The contents of the syringe are sterile. The syringe is equipped with a plunger stopper, finger grip, and plunger rod. The syringe is co-packed in a blister together with sterile 29 G or 30 G needle(s).

The HA has a molecular weight of about one million and is stabilized by adding a minimum amount of 1,4-butanediol diglycidyl ether ("BDDE") to allow formation of a three-dimensional HA molecular network (gel). The chemical stabilizing process does not change the polyanionic character of the polysaccharide chain. Only about 1% of the polysaccharide is stabilized.

3.3 Alternative Practices and Procedures [814.20(b)(3)(iii)]

Patients frequently seek correction of facial contour deformities that are: (1) age-related loss of facial fat or weakening of underlying supportive structures; (2) sun damage in non-pigmented skin; or, (3) related to specific diseases or their treatments that may cause facial wasting, scarring, or structural damage (e.g., prior surgery, anorexia, acne vulgaris, collagen vascular disease). Treatment of photo-damaged skin, with its associated wrinkling and changes in texture and pigmentation, is often accomplished by use of topical moisturizing creams (some of which may contain pharmaceuticals, such as sunscreens or retinoids), chemical or mechanical peeling procedures, or laser resurfacing. These methodologies typically affect epidermal quality but do not treat underlying structural issues. Deeper wrinkles, folds, scars, and other lesions are often treated with surgery (e.g., scar revision, blepharoplasty, face lift, rhytidectomy, permanent silastic implants). Other than implants, these methodologies have the advantage of reducing redundant skin but do not restore the youthful look associated with abundant soft tissue support.

3.4 Marketing History [814.20(b)(3)(iv)]

Restylane was first approved for marketing and sale in September 1996 in the European Union, Iceland, Liechtenstein and Norway (EES). The product has since been approved in several countries worldwide.

Restylane was approved in the United States (U.S.) under PMA P020023 (submitted by Q-Med) on December 12, 2003, and under PMA P040024 (submitted by Medicis) on March 25, 2005.