

Approved Dermal Fillers					
Trade Name (with link to additional information)	Material	Applicant	PMA Number	Decision Date	Approved For
Restylane Lyft with Lidocaine	Hyaluronic Acid, Lidocaine	Q-Med AB	P040024/S099	5/18/2018	Injectable gel indicated for implantation into the deep dermis to superficial subcutis for the correction of moderate to severe facial folds and wrinkles, such as nasolabial folds, subcutaneous to supraperiosteal implantation for cheek augmentation and correction of age-related midface contour deficiencies in patients over the age of 21, and for injection into the subcutaneous plane in the dorsal hand to correct volume deficit in patients over the age of 21.
Revanesse Versa	Hyaluronic Acid	Prollenium Medical Technologies Inc.	P160042	8/4/2018	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults 22 years of age or more
Revanesse Versa +	Hyaluronic Acid, Lidocaine	Prollenium Medical Technologies Inc.	P160042/S003	8/2/2018	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults 22 years of age or more
RHA 2	Hyaluronic Acid, Lidocaine	Teoxane S.A.	P170002	10/19/2017	Injectable gel indicated for injection into the mid-to-deep dermis for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds, in adults aged 22 years or older
RHA 3	Hyaluronic Acid, Lidocaine	Teoxane S.A.	P170002	10/19/2017	Injectable gel indicated for injection into the mid-to-deep dermis for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds, in adults aged 22 years or older
RHA 4	Hyaluronic Acid, Lidocaine	Teoxane S.A.	P170002	10/19/2017	Injectable gel indicated for injection into the deep dermis to superficial subcutaneous tissue for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds, in adults aged 22 years or older
JUVEDERM VOLLURE XC	Hyaluronic Acid	Allergan	P110033/S020	3/17/2017	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) in adults over the age of 21.
Restylane, Refyne, Restylane Defyne	Sodium Hyaluronate	Q-Med AB	P140029	12/9/2016	Restylane Refyne is indicated for injection into the mid-to-deep dermis for the correction of moderate to severe facial wrinkles and folds (such as nasolabial fold) in patients over the age of 21. Restylane Defyne is indicated for injection into the mid-to-deep dermis for the correction of moderate to severe deep facial wrinkles and folds (such as nasolabial fold) in patients over the age of 21.
JUVEDERM VOLBELLA XC	Hyaluronic Acid with Lidocaine	Allergan	P110033/S018	5/31/2016	Injection into the lips for lip augmentation and for correction of perioral rhytids in adults over the age of 21.
RESTYLANE LYFT WITH LIDOCAINE	Hyaluronic acid with lidocaine	Galderma Laboratories	P040024 S073	7/1/2015	Moderate to severe facial folds and wrinkles or in patients over the age of 21 who have age-related volume loss.
RADIESSE	Hydroxylapatite	Bioform Medical, Inc.	P050052/S049	6/4/2015	Subdermal implantation for hand augmentation to correct volume loss in the dorsum of the hands.
RESTYLANE SILK	Hyaluronic Acid with Lidocaine	Valeant Pharmaceuticals North America LLC/Medicis	P040024 S072	6/13/2014	Indicated for lip augmentation and dermal implantation for correction of perioral rhytids (wrinkles around the lips) in patients over the age of 21.
JUVEDERM VOLUMA XC	Hyaluronic Acid with Lidocaine	Allergan	P110033	10/22/2013	Deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.
RESTYLANE-L INJECTABLE GEL	Hyaluronic Acid with Lidocaine	Medicis Aesthetics Holdings, Inc.	P040024 S056	8/30/2012	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles/folds (such as nasolabial folds) and for lip augmentation in those over the age of 21 years.
BELOTERO BALANCE	Hyaluronic Acid	Merz Pharmaceuticals	P090016	11/14/2011	Injection into facial tissue to smooth wrinkles and folds, especially around the nose and mouth (nasolabial folds).
RESTYLANE INJECTABLE GEL	Hyaluronic Acid	Medicis Aesthetics Holdings, Inc	P040024 S051	10/11/2011	Lip augmentation in those over the age of 21 years.
JUVEDERM ULTRA XC AND JUVEDERM ULTRA PLUS XC	Hyaluronic Acid with Lidocaine	Allergan	P050047	1/7/2010	The addition of 0.3% Lidocaine into Juvederm Ultra and Juvederm Ultra Plus.
SCULPTRA AESTHETIC	Poly-L-Lactic Acid (PLLA)	Sanofi Aventis U.S.	P030050 S002	7/28/2009	Use in shallow to deep nasolabial fold contour deficiencies and other facial wrinkles.
EVOLENCE COLLAGEN FILLER	Collagen	Colbar Lifescience I	P070013	6/27/2008	The correction of moderate to deep facial wrinkles and folds (such as nasolabial folds).
PREVELLE SILK	Hyaluronic Acid with Lidocaine	Genzyme Biosurgery	P030032 S007	2/26/2008	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RADIESSE 1.3CC AND 0.3CC	Hydroxylapatite	Bioform Medical, Inc	P050037	12/22/2006	Restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV.
RADIESSE 1.3CC AND 0.3CC	Hydroxylapatite	Bioform Medical, Inc	P050052	12/22/2006	Subdermal implantation for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
ELEVESS	Hyaluronic Acid with Lidocaine	Anika Therapeutics	P050033	12/20/2006	Use in mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
ARTEFILL		Suneva Medical, Inc.	P020012	10/27/2006	Use in facial tissue around the mouth (i.e., nasolabial folds).
JUVEDERM 24HV, JUVEDERM 30, and JUVEDERM 30HV	Hyaluronic Acid	Allergan	P050047	6/2/2006	Use in mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RESTYLANE INJECTABLE GEL	Hyaluronic Acid	Medicis Aesthetics Holdings, Inc	P040024	3/25/2005	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
CAPTIQUE INJECTABLE GEL	Hyaluronic Acid	Genzyme Biosurgery	P030032 S002	11/12/2004	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
SCULPTRA	Poly-L-Lactic Acid (PLLA)	Sanofi Aventis U.S.	P030050	8/3/2004	Restoration and/or correction of the signs of facial fat loss (facial lipoatrophy) in people with Human Immunodeficiency Virus (HIV).
HYLAFORM (HYLAN B GEL)	Modified hyaluronic acid derived from a bird (avian) source	Genzyme Biosurgery	P030032	4/22/2004	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
RESTYLANE INJECTABLE GEL	Hyaluronic Acid	Q-med Ab	P020023	12/12/2003	Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
COSMODERM 1 HUMAN-BASED C	Collagen	Inamed Corporation	P800022 S050	3/11/2003	Injection into the superficial papillary dermis for correction of soft tissue contour deficiencies, such as wrinkles and acne scars.
FIBREL	Collagen	Serono Laboratories	P850053	2/26/1988	The correction of depressed cutaneous scars which are distendable by manual stretching of the scar borders.
ZYPLAST(R)	Collagen	Collagen Corp.	P800022 S011	6/24/1985	Use in mid to deep dermal tissues for correction of contour deficiencies.
ZYDERM COLLAGEN IMPLANT	Collagen	Allergan	P800022	9/18/1981	Use in the dermis for correction of contour deficiencies of this soft tissue.