

FDA Executive Summary - Appendix

Breast Implant Special Topics

**Prepared for the Meeting of the
General and Plastic Surgery Devices**

**Advisory Panel
March 25 and 26, 2019**

The FDA issues a Summary of Safety and Effectiveness Data (SSED) for each approved pre-market approval submission. The SSED describes the data reviewed by the FDA that was used to support approval of the proposed device. The table below contains links to the SSEDs for each breast implant approved for marketing in the US.

PMA Number	Date of PMA Approval	Device Name	Implant Fill and surface type	SSED link
Allergan P990074	5/10/00	Natrelle Saline- Filled Breast Implants	Saline Smooth and Textured – Allergan BIOCELL® using Salt Loss Process	https://www.accessdata.fda.gov/cdrh_docs/pdf/P990074B.pdf
Mentor P990075	5/10/00	Mentor Saline- Filled and Spectrum Breast Implants	Saline Smooth and Textured – Mentor SILTEX® using Stamping Process	https://www.accessdata.fda.gov/cdrh_docs/pdf/P990075B.pdf
Allergan P020056	11/17/06	Natrelle Silicone-Filled Breast Implants	Silicone Gel Smooth and Textured – Allergan BIOCELL® using Salt Loss Process	https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056B.pdf
Mentor P030053	11/17/06	Mentor MemoryGel Breast Implants	Silicone Gel Smooth and Textured – Mentor SILTEX® using Stamping Process	https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030053B.pdf
Allergan P040046	2/20/13	Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone- Filled Breast Implants	Silicone Gel Textured – Allergan BIOCELL® using Salt Loss Process	https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040046B.pdf
Mentor P060028	6/14/13	Mentor MemoryShape Breast Implants	Silicone Gel Textured – Mentor SILTEX® using Stamping Process	https://www.accessdata.fda.gov/cdrh_docs/pdf6/P060028B.pdf
Sientra P070004	3/9/12	Sientra OPUST™ Silicone Gel Breast Implants	Silicone Gel Smooth and Textured – Using Salt Loss Process	https://www.accessdata.fda.gov/cdrh_docs/pdf7/P070004B.pdf
IDEAL P120011	11/14/14	IDEAL IMPLANT® Structured Breast Implant	Saline smooth	https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120011B.pdf

For each approved breast implant, FDA has publicly available patient and physician labeling as it existed at the time of approval. The table below contains links for the labeling at the time FDA approved the implant. For current labeling please see the manufacturers website.

PMA Number	Date of PMA Approval	Device Name	Implant Fill and surface type	Label Link
Allergan P990074	5/10/00	Natrelle Saline- Filled Breast Implants	Saline Smooth and Textured – Allergan BIOCELL® using Salt Loss Process	Patient Labeling Physician Labeling
Mentor P990075	5/10/00	Mentor Saline- Filled and Spectrum Breast Implants	Saline Smooth and Textured – Mentor SILTEX® using Stamping Process	Patient Labeling Physician Labeling
Allergan P020056	11/17/06	Natrelle Silicone-Filled Breast Implants	Silicone Gel Smooth and Textured – Allergan BIOCELL® using Salt Loss Process	Patient Labeling-Augmentation Patient Labeling-Reconstruction Physician Labeling
Mentor P030053	11/17/06	Mentor MemoryGel Breast Implants	Silicone Gel Smooth and Textured – Mentor SILTEX® using Stamping Process	Patient Labeling-Augmentation Patient Labeling-Reconstruction Physician Labeling
Allergan P040046	2/20/13	Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants	Silicone Gel Textured – Allergan BIOCELL® using Salt Loss Process	Patient Labeling-Augmentation Patient Labeling-Reconstruction Patient Labeling-Mini Brochure Physician Labeling
Mentor P060028	6/14/13	Mentor MemoryShape Breast Implants	Silicone Gel Textured – Mentor SILTEX® using Stamping Process	Patient Labeling-Augmentation Patient Labeling-Reconstruction Patient Labeling-Mini Brochure Physician Labeling
Sientra P070004	3/9/12	Sientra OPUS™ Silicone Gel Breast Implants	Silicone Gel Smooth and Textured – Using Salt Loss Process	Patient Labeling-Augmentation Patient Labeling-Reconstruction Physician Labeling
IDEAL P120011	11/14/14	IDEAL IMPLANT® Structured Breast Implant	Saline smooth	Patient Labeling Physician Labeling