

Premarket Approval (PMA)

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Device	COSMETIC TISSUE AUGMENTATION PRODUCT
Generic Name	Implant, Dermal, For Aesthetic Use
Applicant	Anika Therapeutics, Inc. 32 Wiggins Avenue Bedford, MA 01730
PMA Number	P050033
Supplement Number	S001
Date Received	01/03/2007
Decision Date	07/16/2007
Product Code	LMH
Advisory Committee	General & Plastic Surgery
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications/Material
Expedited Review Granted?	No

Combination Product [Yes](#)

Approval Order Statement

APPROVAL FOR: 1) AN INCREASE IN THE BUFFER CONCENTRATION OF THE FINAL PRODUCT FROM 12 MM TO 50 MM SODIUM PHOSPHATE; 2) THE INTRODUCTION OF AN ANTIOXIDANT, I.E., 0.1% SODIUM METABISULFITE, INTO THE FINAL PRODUCT; AND 3) THE INTRODUCTION OF AN 0.5 ML CONFIGURATION OF COSMETIC TISSUE AUGMENTATION PRODUCT (CTA).

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