

K915445 MAALEABLE FACIAL IMPLANTFeb 3, 1992
60 days to decisionK915445 · Product code: **KKY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k915445/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Dec 5, 1991
Decision date	Feb 3, 1992
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Ussc Orthopedics
Location	Warsaw, IN, US
Contact	MARY VERSTYNEN
510(k) history	1 submissions · 1 cleared · 1992-1992

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