

K133046 OMNIPORE CUSTOMIZED SURGICAL IMPLANTSMay 14, 2014
229 days to decisionK133046 · Product code: **KKY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k133046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Sep 27, 2013
Decision date	May 14, 2014
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Matrix Surgical Holdings, LLC/Matrix Surgical USA
Location	Alpharetta, GA, US
Contact	JULIE STEPHENS
510(k) history	2 submissions · 2 cleared · 2014-2018

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