

**K123908 OMNIPORE SURGICAL IMPLANTS AND ACCESSORIES**Jul 31, 2013  
224 days to decisionK123908 · Product code: **KKY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k123908/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Dec 19, 2012
Decision date	Jul 31, 2013
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Matrix Surgical USA</b>
Location	Alpharetta, GA, US
Contact	JULIE STEPHENS
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123908/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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