FDA 510(k) Premarket Notification

CLEARED

K161052 OsteoFab Patient Specific Facial Device

Jul 20, 2016
97 days to decision

K161052 · Product code: **KKY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k161052/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Apr 14, 2016
Decision date	Jul 20, 2016
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oxford Performance Materials, Inc.**
Location	South Windsor, CT, US
Contact	Leigh Ayres
510(k) history	3 submissions · 3 cleared · 2016-2019