FDA 510(k) Premarket Notification

K133809 OSTEOFAB PATIENT SPECIFIC FACIAL DEVICE

CLEARED

Jul 28, 2014
224 days to decision

K133809 · Product code: **KKY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k133809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Dec 16, 2013
Decision date	Jul 28, 2014
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oxford Performance Materials**
Location	South Windsor, CT, US
Contact	LEIGH AYRES
510(k) history	3 submissions · 3 cleared · 2013-2015