FDA 510(k) Premarket Notification

K130350 PROCELLERA

CLEARED

Jul 2, 2013
140 days to decision

K130350 · Product code: **FRO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k130350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Feb 12, 2013
Decision date	Jul 2, 2013
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vomaris Innovations, Inc.**
Location	Chandler, AZ, US
Contact	Mary Maijer
510(k) history	2 submissions · 2 cleared · 2013-2016