

K161953 ReDe MaskFeb 17, 2017
214 days to decisionK161953 · Product code: **PRK** · Anesthesiology
Source: <https://www.510kdatabase.net/k161953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device Indicating An Exhalation Event (PRK)
Date received	Jul 18, 2016
Decision date	Feb 17, 2017
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tereopneuma
Location	San Diego, CA, US
Contact	Warren G. Young
510(k) history	1 submissions · 1 cleared · 2017-2017

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