FDA 510(k) Premarket Notification

K171568 SurFuse Gel, SurFuse Putty, ExFuse Gel, ExFuse Putty

CLEARED

Feb 22, 2018
268 days to decision

K171568 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k171568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	May 30, 2017
Decision date	Feb 22, 2018
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hans Biomed Corporation**
Location	Brea, CA, US
Contact	Lucy Choi
510(k) history	4 submissions · 4 cleared · 2013-2023