FDA 510(k) Premarket Notification

K181721 Ceracell Ortho Foam

CLEARED

Sep 17, 2018
80 days to decision

K181721 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k181721/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jun 29, 2018
Decision date	Sep 17, 2018
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Curasan AG**
Location	Garner,, NC, US
Contact	Gregor Thomas
510(k) history	10 submissions · 10 cleared · 2002-2018

REGULATORY CONSULTANT

Consulting firm	**PaxMed International, LLC**
Contact	Kevin A. Thomas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov