FDA 510(k) Premarket Notification

K212941 Porous Patella

CLEARED

Jan 20, 2022
127 days to decision

K212941 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k212941/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Sep 15, 2021
Decision date	Jan 20, 2022
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Encore Medical, L.P. Dba Djo Surgical**
Location	Austin, TX, US
Contact	Michael A Siano
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k212941/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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