FDA 510(k) Premarket Notification

CLEARED

K190057 DJO Acetabular System

Jun 7, 2019
147 days to decision

K190057 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k190057/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Jan 11, 2019
Decision date	Jun 7, 2019
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Encore Medical, L.P.**
Location	Austin, TX, US
Contact	Teffany Hutto
510(k) history	81 submissions · 81 cleared · 2002-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190057/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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