

K213793 EMPOWR Revision KneeApr 1, 2022
116 days to decisionK213793 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k213793/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | Dec 6, 2021 |
| Decision date | Apr 1, 2022 |
| Days to decision | 116 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213793/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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