

K170753 Acculoc Total Knee SystemMar 23, 2018
375 days to decisionK170753 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k170753/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | Mar 13, 2017 |
| Decision date | Mar 23, 2018 |
| Days to decision | 375 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Rootloc Co., Ltd. |
| Location | Geumcheon-Gu, KR |
| Contact | Jungsun Ha |
| 510(k) history | 2 submissions · 2 cleared · 2018-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170753/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026