

**K261458 ATTUNE Total Knee System**Jun 25, 2026  
55 days to decisionK261458 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k261458/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received         | May 1, 2026  |
| Decision date         | Jun 25, 2026   |
| Days to decision      | 55 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |
| Other names           | ATTUNE Cementless Knee System  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Depuy Ireland UC</b>                 |
| Location       | Ringaskiddy, IE                         |
| Contact        | Paige Myers                             |
| 510(k) history | 50 submissions · 50 cleared · 2018-2026 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261458/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 10, 2026