

**K202194 ATTUNE® Porous Fixed Bearing Tibial Base,
Medialized Dome Patella, and Medialized Anatomic Patella with
AFFIXIUM™ 3DP Technology**Nov 25, 2020
112 days to decisionK202194 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k202194/>**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 | Aug 5, 2020 |
| Decision date | Nov 25, 2020 |
| Days to decision | 112 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Depuy Ireland UC |
| Location | Ringaskiddy, IE |
| Contact | Erin Combs |
| 510(k) history | 47 submissions · 47 cleared · 2018-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202194/> 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 May 15, 2026