

**K253357 b-ONE® Bipolar Head**Apr 13, 2026  
195 days to decisionK253357 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k253357/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Sep 30, 2025
Decision date	Apr 13, 2026
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>B-One Ortho, Corp.</b>
Location	Cedar Knolls, NJ, US
Contact	Allison Gecik
510(k) history	12 submissions · 12 cleared · 2018-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253357/> 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 13, 2026