

**K243634 Maxx Libertas Bipolar Hip Head (Bipolar Hip)**Aug 25, 2025  
273 days to decisionK243634 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k243634/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Nov 25, 2024
Decision date	Aug 25, 2025
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Maxx Orthopedics, Inc.</b>
Location	North Attleboro, MA, US
Contact	Donald Guthner
510(k) history	23 submissions · 23 cleared · 2009-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243634/> 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