

**K082468 APEX HIP SYSTEM BIPOLAR HEAD, MODEL H3-822XX  
AND H3-828YY, XX=OD IN [MM] (38-43), YY=OD IN [MM](44-60)**Feb 18, 2009  
175 days to decisionK082468 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k082468/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Aug 27, 2008
Decision date	Feb 18, 2009
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omni Life Science, Inc.</b>
Location	Raynham, MA, US
Contact	WILLIAM MCCALLUM
510(k) history	21 submissions · 21 cleared · 2006-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082468/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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