

**K122783 PLASMAFIT ACETABULAR CUP AND VITELENE INSERT**Oct 30, 2013  
414 days to decisionK122783 · Product code: **OQG** · Orthopedic  
Source: <https://www.510kdatabase.net/k122783/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hip Prosthesis, Semi-constrained, Cemented, Metal/polymer, + Additive, Porous, Uncemented (OQG)
Date received	Sep 11, 2012
Decision date	Oct 30, 2013
Days to decision	414 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aesculap Implant System, Inc.</b>
Location	Center Valley, PA, US
Contact	JULIE TOM WING
510(k) history	18 submissions · 18 cleared · 2007-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122783/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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