

**K160085 Anatomical Shoulder System, Anatomical Shoulder  
Domelock System, Anatomical Shoulder Fracture System**Mar 8, 2016  
53 days to decisionK160085 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k160085/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Jan 15, 2016
Decision date	Mar 8, 2016
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer GmbH</b>
Location	Warsaw, IN, US
Contact	Roberto Tommasini
510(k) history	43 submissions · 43 cleared · 2004-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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