

**K153398 Comprehensive SRS/Nexel Elbow**Feb 3, 2016  
71 days to decisionK153398 · Product code: **JDC** · Orthopedic  
Source: <https://www.510kdatabase.net/k153398/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Constrained, Cemented (JDC)
Date received	Nov 24, 2015
Decision date	Feb 3, 2016
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet Manufacturing Corp</b>
Location	Warsaw, IN, US
Contact	PATRICIA SANDBORN BERES
510(k) history	93 submissions · 93 cleared · 2004-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153398/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026