

# K240716 AETOS Shoulder System Stemless Humeral Prosthesis

Nov 20, 2024  
250 days to decisionK240716 · Product code: **PKC** · Orthopedic  
Source: <https://www.510kdatabase.net/k240716/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-constrained (PKC)
Date received	Mar 15, 2024
Decision date	Nov 20, 2024
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Smith &amp; Nephew, Inc.</b>
Location	Mchenry, IL, US
Contact	Cassidy Whipple
Website	<a href="http://www.smith-nephew.com/">http://www.smith-nephew.com/</a>
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...