

K040070 ARTELON SPACER CMC-1Sep 21, 2004
251 days to decisionK040070 · Product code: **KYI** · Orthopedic
Source: <https://www.510kdatabase.net/k040070/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Wrist, Carpal Trapezium (KYI)
Date received	Jan 14, 2004
Decision date	Sep 21, 2004
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Artimplant AB
Location	Washington, DC, US
Contact	MARIE MARLOW
510(k) history	7 submissions · 7 cleared · 2003-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040070/> Data sourced from FDA 510(k) public records (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. - Generated May 19, 2026