FDA 510(k) Premarket Notification

K040070 ARTELON SPACER CMC-1

CLEARED

Sep 21, 2004
251 days to decision

K040070 · 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