FDA 510(k) Premarket Notification

K130642 SMR 3-PEGS GLENOIDS

CLEARED

Jun 12, 2013
93 days to decision

K130642 · Product code: **KWS** · Orthopedic
Source: https://www.510kdatabase.net/k130642/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Mar 11, 2013
Decision date	Jun 12, 2013
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lima Corporate S.P.A.**
Location	Winona Lake, IN, US
Contact	CHERYL HASTINGS
510(k) history	64 submissions · 64 cleared · 2011-2026