

K163397 SMR Hybrid Glenoid SystemJun 29, 2017
206 days to decisionK163397 · Product code: **MBF** · Orthopedic
Source: <https://www.510kdatabase.net/k163397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer, Uncemented (MBF)
Date received	Dec 5, 2016
Decision date	Jun 29, 2017
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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