

K211553 Tecomet Global Unite Short Stem InstrumentationAug 4, 2021
77 days to decisionK211553 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k211553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	May 19, 2021
Decision date	Aug 4, 2021
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Symmetry Medical Manufacturing Inc. Db a Tecomet, Inc.
Location	Warsaw, IN, US
Contact	Mike Parrish
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Fdc Services, LLC
Contact	David Furr

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211553/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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