FDA 510(k) Premarket Notification

K192799 Glenoid Baseplate with Screw

CLEARED

Feb 21, 2020
144 days to decision

K192799 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k192799/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Sep 30, 2019
Decision date	Feb 21, 2020
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fx Shoulder USA, Inc.**
Location	Dallas, TX, US
Contact	Kathy Trier
510(k) history	11 submissions · 11 cleared · 2019-2024