FDA 510(k) Premarket Notification

K233482 Equinoxe® Central Screw Baseplate System

CLEARED

Jul 18, 2024
266 days to decision

K233482 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k233482/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Oct 26, 2023
Decision date	Jul 18, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	Liz Howell
510(k) history	186 submissions · 174 cleared · 1986-2026