FDA 510(k) Premarket Notification

K223252 TRULIANT® E-PX Tibial Inserts

CLEARED

Jul 17, 2023
269 days to decision

K223252 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k223252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Oct 21, 2022
Decision date	Jul 17, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TRULIANT® E-PX Patellas

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k223252/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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