FDA 510(k) Premarket Notification

K243817 Scorpio Universal Dome Patella

CLEARED

Feb 6, 2025
56 days to decision

K243817 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k243817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 12, 2024
Decision date	Feb 6, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Scorpio Total Stabilizer Insert; Scorpio-Flex Posterior Stabilized Tibial Insert; Scorpio-Flex Cruciate Retaining Tibial Insert; Scorpio NRG Tibial Bearing Insert – Cruciate Retaining Insert; Scorpio NRG Tibial Bearing Insert – Posteriorly Stabilized Insert

APPLICANT

Company	**Howmedica Osteonics Corp., Dba Stryker Orthopaedics**
Location	Malwah, NJ, US
Contact	Tara Rudrapatna
Website	https://www.stryker.com
510(k) history	31 submissions · 31 cleared · 2010-2026

Howmedica Osteonics Corp., Dba Stryker Orthopaedics is a medical device manufacturer based in Malwah, US. The company operates as part of Stryker, a global medical technology leader. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2010. 97% of submissions focus on Orthopedic devices, including joint replacement systems, knee implants, and hip components. The latest clearance in 2026 demonstrates continued regulatory activity and product innovation. Recent cleared devices include the Triathlon® Total Knee System with multi...