FDA 510(k) Premarket Notification

CLEARED

K261624 Omnifit® 20° Series I Insert

Jul 10, 2026
56 days to decision

K261624 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k261624/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	May 15, 2026
Decision date	Jul 10, 2026
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary
Other names	Omnifit® Crossfire® 10° Series II Insert; Constrained Acetabular Insert; Trident® Crossfire® 0° Polyethylene Insert; Trident ® Crossfire ® 10° Polyethylene Insert;System 12 Crossfire® 10° Insert; Trident® 0° Constrained Acetabular Insert; Trident® Constrained Acetabular Liner;Trident® All Poly Constrained Acetabular Insert; Crossfire® Eccentric Insert 10°; Artisan® Bone Plug;UHR® Universal Head Bipolar Component

APPLICANT

Company	**Howmedica Osteonics Corp., Dba Stryker Orthopaedics**
Location	Malwah, NJ, US
Contact	Elizabeth Jodon
Website	https://www.stryker.com
510(k) history	32 submissions · 32 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...