FDA 510(k) Premarket Notification

CLEARED

K102282 THE VARIA FIBULA LOCKED PLATING SYSTEM LINE EXTENSION ADDITION OF STRAIGHT PLATES

Dec 7, 2010
117 days to decision

K102282 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k102282/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 12, 2010
Decision date	Dec 7, 2010
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Howmedica Osteonics Corp., Dba Stryker Orthopaedics**
Location	Malwah, NJ, US
Contact	STEPHANIE FITTS
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...