FDA 510(k) Premarket Notification

CLEARED

K161863 ReUnion Reversible Fracture System (RFX), ReUnion Reverse Shoulder Arthroplasty (RSA), ReUnion Total Shoulder Arthroplasty (TSA)

Nov 23, 2016
140 days to decision

K161863 · Product code: **KWS** · Orthopedic
Source: https://www.510kdatabase.net/k161863/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Jul 6, 2016
Decision date	Nov 23, 2016
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker GmbH**
Location	Selzach, Solothurn, Ch, CH
Contact	Saad Attiyah
Website	https://www.stryker.com
510(k) history	54 submissions · 54 cleared · 2015-2026

Stryker GmbH is a medical device manufacturer based in Selzach, Solothurn, Switzerland. The company specializes in orthopedic surgical devices and implants. Stryker GmbH has received FDA 510(k) clearances from total submissions since 2015. The company's regulatory portfolio is entirely focused on orthopedic devices, reflecting its core expertise in fracture fixation and surgical instrumentation. The latest clearance was granted in 2026, demonstrating continued active development and market engagement. Recent cleared devices include femur and humerus nailing systems, dista...