FDA 510(k) Premarket Notification

K103010 STRYKER PATIENT SPECIFIC POLYMER IMPLANT

CLEARED

Oct 26, 2010
14 days to decision

K103010 · Product code: **KKY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k103010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Oct 12, 2010
Decision date	Oct 26, 2010
Days to decision	14 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...