FDA 510(k) Premarket Notification

K122053 SHAPEMATCH CUTTING GUIDE

CLEARED

Oct 24, 2012
103 days to decision

K122053 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k122053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Jul 13, 2012
Decision date	Oct 24, 2012
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
Contact	TAMMY WHARTON
510(k) history	124 submissions · 121 cleared · 1976-2023

Stryker Corp. is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, implants, and patient safety technologies used globally across multiple medical specialties. Stryker has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company maintains active regulatory engagement, with its latest clearance in 2023. Its product portfolio spans orthopedic devices, neurosurgical implants, surgical instruments, and endoscopy systems, reflecting a broad pr...