FDA 510(k) Premarket Notification

K123486 TRIATHLON TRITANIUM TIBIAL BASEPLATE

CLEARED

May 3, 2013
171 days to decision

K123486 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k123486/

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	Nov 13, 2012
Decision date	May 3, 2013
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker**
Location	Portage, MI, US
Contact	AUDREY WITKO
Website	http://www.stryker.com/
510(k) history	92 submissions · 92 cleared · 2006-2023

Stryker is a family of eight-wheeled armored fighting vehicles derived from the Canadian LAV III. The vehicles are produced by General Dynamics Land Systems-Canada for the United States Army in London, Ontario. This historical record documents FDA 510(k) cleared devices from total submissions between 2006 and 2023. The company's regulatory portfolio focused primarily on General & Plastic Surgery devices, including advanced imaging systems, LED light sources, and surgical visualization equipment. The company has been inactive, with no clearances recorded in more than five ...