FDA 510(k) Premarket Notification

K121029 METS MODULAR DISTAL FEMUR

CLEARED

Sep 19, 2012
167 days to decision

K121029 · Product code: **KRO** · Orthopedic
Source: https://www.510kdatabase.net/k121029/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Apr 5, 2012
Decision date	Sep 19, 2012
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stanmore Implants Worldwide , Ltd.**
Location	Washington, Dc, DC, US
Contact	NANCY C MACDONALD
510(k) history	8 submissions · 8 cleared · 2011-2015