FDA 510(k) Premarket Notification

K140898 PATIENT SPECIFIC DISTAL FEMORAL

CLEARED

Jan 20, 2015
287 days to decision

K140898 · Product code: **KRO** · Orthopedic
Source: https://www.510kdatabase.net/k140898/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Apr 8, 2014
Decision date	Jan 20, 2015
Days to decision	287 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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