

**K140900 PATIENT SPECIFIC SMILES TOTAL KNEE REPLACEMENT**Feb 12, 2015  
310 days to decisionK140900 · Product code: **KRO** · Orthopedic  
Source: <https://www.510kdatabase.net/k140900/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Apr 8, 2014
Decision date	Feb 12, 2015
Days to decision	310 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stanmore Worldwide Implants , Ltd.</b>
Location	Plymouth, MA, US
Contact	SAMANTHA SHELLEY
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140900/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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