FDA 510(k) Premarket Notification

CLEARED

K133370 REMEDY HIP STEM, PEGASUS HIP STEM, EVOLVE HELIOS HIP STEM, EVOLVE MASTERS HIP STEM, EVOLVE DISTAL CENTRALIZER, EVOLVE CE

Jul 22, 2014
260 days to decision

K133370 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k133370/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Nov 4, 2013
Decision date	Jul 22, 2014
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Signature Orthopaedics Pty Limited**
Location	Nsw, AU
Contact	DECLAN BRAZIL
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k133370/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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