Hip Prosthesis Data - Stem

Please read the guidance notes before filling out this sheet

Prosthesis details		
Manufacturer		Sol Orthopaedics
UK Distributor (if different)		
Stem brand (please name all variants or versions within the Brand)		Pluto Hip Stem
Product Codes and Sizes		Please provide on a separate sheet detailing individual product numbers and descriptions in Excel format
Images of products attached, including all variants	Yes	*Photo taken against white background, best size 300x300px, resolution 200dpi. This could be used on the ODEP website.*
The date (year) of the first ODEP award for this product		
Date of this submission		
Please confirm for the product codes listed		
Data presented relates to use in primary hip replacement only	Yes	
Material composition is identical	Yes	
Surface finish and coating is identical	Yes	
Taper / trunnion design is identical	Yes	All 12/14 tapered Sol Orthopaedics Heads
Proximal Geometry		✓Collared ✓Collarless
If present, material of modular neck is identical	N/A	
If you answer 'no' to any of the above please explain and ensure it is clear what differences exist and the product codes they relate to		
Technical design features for the product codes listed		
Fixation		☐Cemented ✓Cementless
If cementless, please give details of the surface finish (e.g. grit blasted / sintered bead, with or without HA), including full or partial coating		Proximal HA coating over a macrofinish substrate
Modularity		☐Monobloc head ✓Modular head ☐Modular neck
Stem material(s) and manufacturing method(s)		Titanium Alloy (Ti-6Al-4V) forged
Offset ranges (eg standard, high offset)		Standard, High Offset, Short Neck
Femoral stem length range (minimum to maximum)		105-185mm
Compatible head(s) - materials and manufacturing methods		Co-Cr-Mo Alloy (Mercury Heads), wrought. Zirconia Stabilised Alumina (CeramStar Venus), sintered. Alumina (CeramStar Mars), sintered.
Femoral head(s) - sizes range (minimum to maximum)		22-40mm
Other design features that may affect implant survival	Yes	
If you answered 'Yes', please explain		Proximal Lateral Anti-Rotation Fin
Compatible Acetabular cups and liners.		All Sol Orthopaedics manufactured acetabular cups
Stem design history		
Date of first clinical use		
Date of the original CE mark		
Date of the latest CE mark renewal (new MDR / UKCA)		
Date of first clinical use in UK		
Have any design changes been made?	No	
If yes, please give details **and dates** of modifications	1	
	2	
	3	
Please confirm that all data submitted relates to the latest design		
Yes ☐		
No (please give justification) ☐		
Please confirm that the revision rates for all stem versions listed in the product codes falls within the benchmark for which you have applied		✓Confirm ☐Cannot confirm
(NB You may be asked to provide supporting evidence)		
Benchmark claimed (select from dropdown list)	→	3A
Does this product have a current ODEP rating?	No	
Current rating (if applicable)	→	
Year rated	→	
If known, what is the listing URL (the exact address of the webpage) on the ODEP website?		http://www.odep.org.uk/product.aspx?pid=
Beyond Compliance Product	No	
Please confirm a list of UK implanting centres is attached	Yes	
Is the clinical data submitted for this stem representative of the results of all studies conducted in relation to it?	Yes	
If 'no', please give details of, and reasons for, data that has been omitted that does not indicate similar or better results than that submitted on the attached Clinical Data Templates		

Have any Field Safety Notices (**FSN**s) or similar notices been issued / served for this product since the current rating was given? If "Yes", please provide further details in the comments box ***NB!*** *ODEP will make a decision as to whether this information to have a bearing on the submission, but knowlingly failing to declare any FSNs could lead to the rating being removed.*	
Have RSA studies been conducted on this prosthesis? If "Yes", please attach details of date of study(s), number of patients evaluated, where the study was undertaken and results including time interval between first and second X-Ray ***NB!*** *ODEP will welcome details of RSA studies as they feel they are important but it is realised that they are not always available and failure to produce RSA studies will not lead to the submission being rejected*	