



**Australian Government**  


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**Department of Health**  
 Therapeutic Goods Administration

File Number: 2014/020357

**Peter Witherspoon - Regulatory Affairs Manager**  
**Lima Orthopaedics Australia Pty Ltd**  
**Unit 1, 40 Ricketts Road**  
**MOUNT WAVERLEY VIC 3149**

**CTN Scheme (Devices): Acknowledgement of New Trial**

Your notification to conduct a clinical trial under the Clinical Trial Notification (CTN) Scheme, pursuant to Regulation 7.1 of Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, has been received by the Office of Scientific Evaluation (OSE).

Trial Number: 2014/0417  
 Protocol Number: MHS20140211-3

Therapeutic Good(s):

<b>Name of Device</b>	<b>Trade Name</b>	<b>Code Name</b>	<b>Strength</b>
Master SL Femoral Stem Standard Poro + HA coated (sizes 1-13)	N/A	N/A	N/A
Master SL Femoral Stem Lateralised Poro + HA coated (sizes 1-13)	N/A	N/A	N/A
Master SL Femoral Stem Standard Poro coated (sizes 1-13)	N/A	N/A	N/A
Master SL Femoral Stem Lateralised Poro coated (sizes 1-13)	N/A	N/A	N/A

It is noted that:

- i. the approval of the goods for this trial was given in accordance with Item 2.3 of Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* by the body or organisation conducting the trial at each additional site.
- ii. the representative of the Ethics Committee for each additional site has certified that the Committee is constituted and operates in accordance with the NHMRC “National Statement on Ethical Conduct in Human Research” has considered this clinical trial, and has provided advice to the body or organisation conducting the trial.

The Therapeutic Goods Administration has not carried out an assessment of the quality, safety or efficacy of any drug product in relation to this notification.

Please note that, in the event that the Secretary of the Commonwealth Department of Health becomes aware that to undertake or continue the clinical trial would be contrary to the public interest, the Secretary has the authority to direct that use of the drug product(s) for this clinical trial must cease.

A form “CTN and CTX Trial Completion Advice” is enclosed. Please fill out and return this form after the Clinical Trial has completed.

Christina Kotowski  
 Experimental Products Section  
 Office of Scientific Evaluation  
 16 June 2014



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## **CTN Scheme (Devices): Clinical Trial Site List**

This document lists all sites acknowledged to date for the following clinical trial:

**Sponsor: 52569 - Lima Orthopaedics Australia Pty Ltd**

**Protocol Number: MHS20140211-3**

**Trial Number: 2014/0417**

<b>Date Acknowledged</b>	<b>Site Name</b>	<b>State</b>
16 June 2014	Mater Health Services North Queensland Ltd	QLD



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**CTN AND CTX CLINICAL TRIAL  
COMPLETION ADVICE**

This form should be used by sponsors of clinical trials to notify the TGA of completion of trials of medicines, biologicals and medical devices conducted under the CTN and CTX Schemes.

**Sponsor and Clinical Trial Details**

Sponsor	Lima Orthopaedics Australia Pty Ltd		
Client ID	52569	Scheme <i>(Delete as appropriate)</i>	CTN/CTX
Protocol Number	MHS20140211-3	Trial Number	2014/0417
Date Completed:			

**Reason for completion (Select one only)**

Concluded normally	<input type="checkbox"/>	Premature termination - safety*	<input type="checkbox"/>
Insufficient recruits	<input type="checkbox"/>	Premature termination - other*	<input type="checkbox"/>
Directed by TGA	<input type="checkbox"/>	Directed by HREC	<input type="checkbox"/>

*\*Please give details. Attach additional page if insufficient space.*

Print Name	<input type="text"/>	Position	<input type="text"/>
Signature	<input type="text"/>	Phone	<input type="text"/>
	/ /	Fax Number	<input type="text"/>

**Send this form to:**  
Experimental Products Section  
Office of Scientific Evaluation  
Therapeutic Goods Administration