Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

3/02/2010
Submission ID: DA-2010-00047-7

Lima Orthopaedics Australia Pty Ltd
PO Box 141
GLEN IRIS VIC 3146

Attention: [redacted]

Notification of Inclusion of a Medical Device
Application for inclusion in the ARTG: DV-2009-DA-14567-3
Sponsor's Reference: Lima Orthopaedics - SMR System glenoid components
ARTG Identifier: 168581

I am the delegate of the Secretary for the purposes of section 41FF of the *Therapeutic Goods Act 1989* (the Act).

Your application to include the above mentioned device on the Australian Register of Therapeutic Goods (ARTG) was successful. An automatic email has also been sent to the applicant informing them of this decision.

The device has been included on the ARTG, subject to the conditions stated on the ARTG Certificate. This certificate may now be downloaded and printed by the Sponsor (or their Agent) by logging in to the TGA eBusiness Services (eBS) website <www.ebs.tga.gov.au>. The TGA will not be issuing a hard-copy of this certificate.

Reasons for the decision

The decision to include these medical devices on the ARTG was based on the information provided in the application, and your declaration that the matters certified in the application under section 41FD of the Act are complete and correct.

Annual charges

The TGA Finance Services Group will issue an invoice for annual charges. The inclusion of these devices commenced on the date specified in the ARTG Certificate. The continued inclusion on the ARTG is subject to payment of annual charges, and the conditions placed on the inclusion.

Ongoing monitoring of quality, safety and performance

Medical devices on the ARTG are subject to ongoing monitoring of their quality, safety and performance. These medical devices may be chosen, at any time as part of a random product review, to verify the matters certified under section 41FD of the Act, or may be subjected to a targeted product review if there are any potential or real risks identified with the use of the device.

Sponsors' ongoing regulatory responsibilities

Australian sponsors of medical devices have ongoing regulatory responsibilities for the medical devices they supply to the Australian market.

These responsibilities include but are not limited to:

- Ensuring that any documentation relating to the medical device, or sample of the medical device, can be provided to the TGA upon request, and within the specified timeframes;
- Ensuring the advertising of the medical devices comply with the advertising requirements specified under Chapter 5 of the Act, and is consistent with the intended purpose for the device as certified under section 41FD. Advertising direct to consumers (other than healthcare professionals) must also comply with the Therapeutic Goods Advertising Code. A copy of this code can be found on the Therapeutic Goods Advertising Code Council website at <http://www.tgacc.com.au>. It is important to note that any advertising material submitted during the pre-market assessment is not assessed for compliance with the advertising requirements. The advertising material is only used to assist with clarifying the manufacturer's intended purpose for the device;
- Ensuring that any serious problem or adverse event associated with the use of the device is reported to the TGA within the timeframes specified under section 41MP of the Act. Further guidance regarding the obligations to report adverse events is available in Guidance Document 11 –Post Market Activities on the TGA website at <http://www.tga.gov.au/docs/html/devguid11.htm>; and
- Ensuring that any recall of the device is undertaken in accordance with the Uniform Recall Procedure for Therapeutic Goods and is coordinated by the Recalls Unit of the TGA. A copy of the recall procedure is available on the TGA website at <http://www.tga.gov.au/docs/html/urptg.htm>.

Yours sincerely,

[redacted]
Delegate of the Secretary under s41FF of the *Therapeutic Goods Act 1989*
Office of Device of Blood & Tissues