



PO Box 100 Woden ACT 2606 Australia
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Contact Officer: Karissa Slavin

TGAIN: 141204
ENT ID: 14455

Ebos Health & Science Pty Ltd
PO Box 386
ALEXANDRIA NSW 2015

ATTENTION: John Green

NOTIFICATION OF DECISION TO LIST THERAPEUTIC GOODS

Further to your application to list:

Product Name: MARGRON FEMORAL HEAD

Manufacturer: OSTEOIMPLANT TECHNOLOGY INC – ENT ID: 32083

in the Australian Register of Therapeutic goods, under the listing name:

**EBOS HEALTH & SCIENCE GRAFTS IMPLANTS & PROSTHESES STERILE
{OSTEOIMPLANT TECHNOLOGY MD USA}**

These goods shall be listed subject to the conditions as stated in the Certificate of Listing related to this Notification.

It is a condition of listing specified under Regulation 16 (Schedule 6) of the Therapeutic Goods Act 1989, and the responsibility of the sponsor, that the labels for the goods comply with TGO 37 – 'General Requirements for Labels for Therapeutic Devices'.

Please note the labels you have submitted are deficient in that:

- The address of manufacturer or sponsor does not appear on the label.

Please do not send the amended label(s) to the TGA but ensure that the deficiencies are corrected 'prior' to supply of the goods. Compliance to Therapeutic Goods Order 37 requirements will be subject to post market audits and penalties apply for non-compliance.

The TGA Business Management Unit will issue an invoice for annual charge. The listing of the goods will commence on the day specified for the purpose in the Certificate of Listing. The goods may not be supplied prior to this date. Continued listing will be subject to payment of the annual charge.

All future communications regarding the product should include the **Listing Number AUST L 76705** as a reference.



Delegate of the Secretary
Device Listing Section
Conformity Assessment Branch

E/PREMARKT/LISTING/NOTIF00/141204KS.DOCT

2nd. November 2000

ENC: Certificate of Listing

FOR INFORMATION - GMP Pre-clearance

The Device Listing Section no longer assesses evidence of Good Manufacturing Practice. To expedite your applications it is recommended that sponsors obtain a GMP pre-clearance from the GMP Auditing and Licensing Section (GMPALS) of the TGA prior to submitting applications for listing of therapeutic devices. A GMP pre clearance will ensure that applications are not unnecessarily delayed. This is a free service offered by GMPALS unless it is necessary to contact other Regulatory Agencies in which case a fee will apply. For further information on this service please contact Vicki Partridge, (02) 6232 8627.



Therapeutic
Goods
Administration

PO Box 100, Woden, ACT 2606, Australia
Telephone: (06)232 8444. Fax: (06)232 8581

TGAIN: 141204

CERTIFICATE OF LISTING

Listing Name of Therapeutic Goods:

EBOS HEALTH & SCIENCE GRAFTS IMPLANTS & PROSTHESES
STERILE {OSTEOIMPLANT TECHNOLOGY INC MD USA}

ARTG Listing Number:

AUST L 76705

Commencement Date of Listing

2 November 2000

Sponsor:

EBOS HEALTH & SCIENCE P/L

Sponsor Enterprise ID: 14455

**The above Therapeutic goods are listed in the Australian Register
of Therapeutic goods subject to the following conditions: -**

1. *Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*
2. *Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.*

CERTIFIED ORIGINAL