PORTLAND SQUARE PTY LTD
ACN 001 243 434

Suite 3 Level 5
St George Private Hospital
1 South Street
KOGARAH NSW 2217

Tel: +61 2 9588 2121
Fax: +61 2 9587 1014

THERAPEUTIC GOODS ADMINISTRATION
THERAPEUTIC DEVICES BRANCH (No. 2)
22 FEB 1999
RECEIVED

18/2/99

Keith M Smith
Device Registration and Assessment Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Dear Mr Smith,

Please find enclosed a copy of the report by Unisearch on the Margron Total Hip Replacement detailing product background and testing information to date. This comprehensive document I hope will provide an insight into the product and the work undertaken in arriving at this stage of development.

At present, further static and cyclic fatigue testing is being conducted by William R Walsh, Ph.D at the University of NSW Orthopaedic Research Laboratories. I understand that all test processes are to ISO standards in relation to hip testing. The prosthesis is available for use in Australia with clinical data results from implanted devices continually being generated.

Portland Square Pty Ltd and MAC Instruments Pty Ltd, the manufacturers' subcontractor, are currently involved in discussions on the set up a combined new company. With this being the case we may be looking toward a longer term goal of installing an ISO / EN Quality Assurance System and hence the application of Annex III plus Annex VI.

I hope to determine our intentions for either CE Marking within the next few days. Having clarified this, I would suggest a meeting to assist with the planning of our assessment application.

Regards,

Andrea Tattam