TGA Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Woden Telephone: (06) 289 1555. Fax: (06) 289 8709
Symonston Telephone: (06) 239 8444. Fax: (06) 239 8605

COMMONWEALTH DEPARTMENT OF HEALTH, HOUSING, LOCAL GOVERNMENT AND COMMUNITY SERVICES

Dr R Sekel
Director
Portland Square Pty Ltd
42 Montgomery Street
Kogarah NSW 2217

Dear Dr Sekel

This letter acknowledges receipt of your notification and fee, dated 17 June 1994, for the clinical trial under the Clinical Trial Notification (CTN) Scheme (protocol number 93/37 Sekel ) pursuant to Schedule 5A of Regulation 12 of the Therapeutic Goods Regulations. This application for the trial of device St. George Total Contact Hip Replacement for hip replacement for degenerative changes of the hip secondary to osteoarthritis or post-traumatic has been allocated CTN number 05/94. Your receipt for the application fee is attached.

The requirements to conduct the trial have been fulfilled including Southern Sydney Area Health Service Ethics Committee approval on the 12 April 1994 and that the Secretary of this committee has certified that the committee is constituted and operates in accordance with the NHMRC Statement on Human Experimentation and Supplementary Notes.

You are reminded that the Therapeutic Goods Administration (TGA) has not carried out an assessment of the quality, safety and efficacy of this product in connection with this or any other notification. All suspected adverse events occurring in relation to the trial should be reported by the investigator to the sponsor. The sponsor should also report to the IEC any relevant trial stopped overseas or withdrawals from the market for safety reasons.

If a trial is discontinued for any reason, the Chief Medical Officer of the Therapeutic Devices Branch should be notified and given the reasons for the discontinuation.

In the event that the Secretary becomes aware that to undertake or continue the clinical trial would be contrary to the public interest, he has the authority under the Therapeutic Goods Regulations, Schedule 5A to direct that the use of the St George Total Contact Hip Replacement for this clinical trial must cease.

Yours sincerely

C K -

Dr C W Kelman
Chief Medical Advisor
Therapeutic Devices Branch

28 June 1994

S:\CLINICAL\CTN_APRV.TMP