TGA Therapeutic Goods Administration

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COMMONWEALTH DEPARTMENT OF HUMAN SERVICES AND HEALTH

[redacted]

Dear [redacted]

Clinical Trial Notification 0017/95

This letter acknowledges receipt of your notification and fee, dated 18 May 1995, to conduct clinical trials under the Clinical Trial Notification (CTN) scheme pursuant to Schedule 5A of Regulation 12 of the Therapeutic Goods Regulations. This application for the trial of device **Stentor Endoluminal Prosthesis** has been allocated **CTN number 0017/95.** Your receipt for the application fee is attached.

It is acknowledged that this study will be conducted as a multi-centre trial at the following institutions :

1. [redacted]
2. Monash Medical Centre, Clayton, Melbourne

For each institution, this notification will only become effective once the respective Institutional Ethics Committee has approved the conduct of the trial. The Ethics Committee Approval letter should be signed by the Chairperson of the Ethics Committee or an authorised administrative officer. The letter should clearly state the clinical trial and protocol number being approved and it should certify that the committee is constituted and operates in accordance with the NHMRC Statement on Human Experimentation and Supplementary Notes. **A copy of this Ethics Committee Approval letter must be forwarded to the Therapeutic Devices Branch prior to commencing the trial at each institution.**

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 Stentor Endoluminal Prosthesis for this clinical trial must cease.

Yours sincerely

[redacted]

Acting Chief Medical Advisor
Therapeutic Devices Branch

26 June 1994