Therapeutic Devices

Additional Information required if not present in Protocol:

Describe the nature of the device, including details of the design, composition, specification, mode of action and application of the device: Include whether of human or animal origin:

Is the device registered on the Australian Register of Therapeutic Goods (ARTG) Yes / No

Is the device being considered under the Clinical Trial Exemption (CTX) Scheme Yes / No

Is the device being considered under the Clinical Trial Notification (CTN) Scheme Yes / No

Please provide documentary evidence for the above

Signature from Andrew Moorhouse (p3007) indicating approval from Medical Engineering and Physics, to be obtained before submission to HREC:

Signature..... Date: / / .

Describe previous experiences relevant to the safety and efficacy of the device

Long-term follow-up – describe the intended procedures to ensure long-term follow-up of trial participants

Please provide (tick if present)

- ☐ relevant correspondence with other regulatory authorities (includes statements of the commercial or investigational status of device overseas)
- ☐ Relevant correspondence with other ethics committees
- ☐ All information concerning previous product recalls
- ☐ For devices of human or animal origin, provide evidence of compliance with Quarantine, where appropriate