Your ref: CB2/PL/HS
Our ref: SPH04-GC-DF/hl/0012
Hon Michael Mak
Panel Chairman
The Panel on Health Services of the Legislative Council
Legislative Council Building,
8 Jackson Road,
Central, HK.

12 March 2004

Dear Hon Michael Mak,

Regulation of medical devices

In response to your request for our opinion on the proposed regulation on medical devices, I wish to provide the following opinion with reference to the Administration's paper to the Panel.

The principles and main framework of regulation are supported. Regulation will undoubtedly protect the interest and safety of the public. I wish only to bring to your attention the following:

1. The division between Class I (low risk) and Class II (medium risk) devices is indistinct. There should be a more detailed list clearly separating the items belonging to these classes, and for that matter, all 4 classes.
2. There is no definite guideline on the conduct and regulation of clinical trials for these devices which are still of unproven value and safety. Hospitals and teaching institutes need to conduct such trials under internationally agreed standards of good clinical (research) practice.

With adequate control but minimal impediment, the proposed regulatory framework will further strengthen the confidence of our community in using/ purchasing medical device and related services.

Yours sincerely,

Dr. David Fang
Medical Superintendent
St. Paul's Hospital