



香港眼科醫學院

# The College of Ophthalmologists of Hong Kong

(Incorporated in Hong Kong with limited liabilities)  
a Constituent College of the Hong Kong Academy of Medicine



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Mar 19, 2004

Dear The Honorable Michael Mak Kwok-fung  
Health Panel,  
Hong Kong Legislative Council  
HKSAR

Dear the Honorable Mak,

## Regulation of Medical Devices in Hong Kong (Consultation Document July 2003)

The College of Ophthalmologists of Hong Kong (the "College") shows a great concern about the safe use of laser systems or machines on human subjects in Hong Kong. We are glad to see that the Department of Health has put forward a consultation paper on this area and in collecting the opinions from the public.

### The College recognizes that:

1. Laser surgery, treatments or similar kinds are just like other surgical or medical procedures which could cause serious body damages or complications. Some of the adverse events may not be reversed by further treatments, such as loss of vision, deep skin burns.
2. Wrong application of laser treatment may disturb the original pathology of the disease which might affect the subsequent exact diagnosis and management.
3. Non-health care providers are not in the right position to operate a laser machine or to execute laser treatment in view of their lack of training and knowledge on human structure, anatomy and pathology. Moreover, they are generally not regulated by statutory governing bodies, like the Medical Council, and their standard or code of practice are very variable which will make the public less protected from the misuse or overuse of laser treatments or applications.

### The College strongly believes that:

1. All laser machines or similar kinds should be categorized as medical devices of Class IV because of their powerful energy delivery in design and potential, irreversible damages on human bodies.
2. The practice of laser machines or similar kinds on human bodies must remain or be restricted in the domain of the registered medical and dental practitioners. The medical and dental practitioners should take full liability for the correct operation of the medical laser machines and to protect the patients' interest to the greatest extent.

We judge a responsible and accountable Government should share our viewpoints and will take necessary and appropriate legislation to safeguard the health affair of the public.

Thank you for your attention.

Yours sincerely,

Professor Dennis SC Lam  
President  
The College of Ophthalmologists of Hong Kong