ivoclar vivadent
passion vision innovation

Received 8/12/10.

3rd December 2010

The Manager
Office of Devices Authorisation
Therapeutic Goods Administration
P O Box 100
WODEN ACT 2606

Dear Sir,

Re: TGA Proposed Regulatory Reforms

Further to abovementioned subject matter, I wish to raise the following issues:-

Proposal 3(i) ARTG inclusion changes:-

The proposal obviously changes the existing arrangements and will cost a lot of time and energy. The "IT" costs for individual companies will be substantial both at the outset and the future.

Proposal 3(ii) Enhancing the Identification of approved devices:-

This proposal will increase the cost to us substantially and will increase the dispatch time to the client. I see this cost will need to be passed on – when you consider the many small consumables that we sell to the profession we see this proposal as impractical and expensive. The ongoing costs will also be significant and will eventually be borne by the end user – ie: the patient.

I trust that you take into consideration our input before your proposed regulatory reforms become reality.

Yours faithfully,
Ivoclar Vivadent Pty Ltd

Dr Peter Lobo
Executive Manager – Sales & Marketing

CC. Phil Jolly

Certified System Quality ISO 9001 SAI GLOBAL

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