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17th December 2010

Office of Devices Authorisation
Therapeutic Goods Administration
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Woden ACT 2606
Email. devices@tga.gov.au

To whom it may concern,

In response to the TGA's discussion paper on proposed changes to the medical devices regulatory framework, we would like to raise the following issues with in relation to Proposal 3 (i) and 3 (ii).

With respect to proposal 3(i), in which sponsors are required to itemise the devices and/or various models that are supplied under the same ARTG entry, we have the following comment. We believe that this new legislation would place an additional burden on sponsors like ourselves in the dental industry as we would be required to submit updates for minor changes to a model. In some instances, a minor change may have no impact on the devices' use or operation and subsequently no affect on the patient health outcomes. It is imperative that the TGA defines the specifics of a 'model' and when sponsors must notify the TGA of changes.
Should this reform come into effect, it would substantially alter the existing regulatory arrangements for our business and other sponsors in the dental industry and it would result in additional costs.

With respect to proposal 3(ii), in which sponsors of medical devices would be required to publish the ARTG No that accompanies a medical device, we have the following comment: As a member of the dental industry, a large proportion of our products are manufactured overseas. Introducing changes to either the packaging or the product itself would result in time delays and a substantial initial cost to our business and ongoing costs. Should this proposal be adopted it would considerably alter the existing regulatory arrangement for businesses.

Yours faithfully

Elizabeth Bozinovska