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stryker®

South Pacific

29th July 2011

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600, Australia

Re: Inquiry into The Regulatory Standards for the Approval of Medical Devices

Stryker Australia would like to take the opportunity to submit a response to the Senate Standing Committee on Community Affairs regarding the Inquiry into The Regulatory Standards for the Approval of Medical Devices. Stryker has already contributed to the submitted response of the Medical Technology Association of Australia, and is in agreement with that submission, however wishes to provide additional information in regard to section (e) of the listed Terms of Reference: *the safety standards and approval process for devices that are remanufactured for multiple use.*

Stryker, along with many hospitals in the healthcare system, believes that the remanufacturing of specific and appropriate expensive medical devices that are marked for single use only, can contribute towards relieving costs in an overburdened health system. For this purpose, Stryker acquired Ascent Healthcare, a global leader in single use device (SUD) remanufacturing, in December 2009 and has been working with the TGA in Australia to attain inclusion on the ARTG for a group of SUDs. Since its inception almost two decades ago, Ascent has safely remanufactured more than 50 million SUDs and currently has a customer base of more than 2000 hospitals and surgical centres throughout the United States and has more than 90 groups of products regulated through the FDA. In 2010 alone, Ascent saved hospitals US$185 million, and diverted 3 million kilos of medical waste.

Historically, single-use devices have been branded single-use for one of two main reasons:

1. They can genuinely only be used once; or
2. They have only been validated for a single use.

While Stryker understands that there is a large range of products that can genuinely only be used once, there is also a significant number of products that the original equipment manufacturers (OEMs) have only validated for a single use, and that with the correct and validated remanufacturing processes in place, could be validated as safe and effective for an additional use.

Remanufacturing in the form that Ascent represents, utilises a certified Quality Management System in a process involving disassembling, cleaning, retesting, resterilising, revalidating, and repackaging of a non-implantable device which the OEM has validated for a single use, in order to render that device safe and effective for the original intended purpose. This is in contrast to the reprocessing which occurs outside of a validated Quality Management System, without the rigorous testing and revalidation aforementioned, and, most importantly, without the assessment or approval of a regulatory body such as the TGA. Anecdotally, such reprocessing has been known to occur in hospitals, without validated protocols or appropriate functionality testing. The intention of this practice would be cost-saving, but the outcome is a compromise of untested safety and effectiveness.

The term “for multiple use” needs to be put into perspective, as a remanufactured product is only used once more, before being returned to the remanufacturer and passed again through the rigorous remanufacturing and revalidation process. Products are validated to be remanufactured each time for a limited number of cycles based on prior research and testing. If any product does not thoroughly meet the established testing at any time, even within those limited number of cycles, it is rejected and not returned to the hospital for a further use.

The TGA introduced a regulatory framework for the remanufacture of SUDs in December 2003 with a final compliance date of March 2006; when a device is re-manufactured for re-use then the nature of the process deems the person a manufacturer under the Therapeutic Goods Act and must therefore comply with the therapeutic goods legislation relating to the manufacture of medical devices. This can require the manufacturer to:

- Undergo Conformity Assessment by the Therapeutic Goods Administration (TGA);
- Obtain a TGA Conformity Assessment Certificate; and
- Include the remanufactured SUDs on the Australian Register of Therapeutic Goods (ARTG).

In particular, the conformity assessment process may include rigid review of documentation and an onsite audit by the TGA to ensure the manufacturer’s compliance to ISO 13485:2003, assessment of compliance to the Essential Principles for safety and performance, and to assess design dossiers or design history files.

Stryker supports the rigorous assessment of persons as manufacturers before they can supply remanufactured goods in Australia. Stryker believes this is the only avenue to ensure that non-validated and non-approved reprocessing does not occur.

Stryker is also aware that the availability of safe and effective remanufactured medical devices will preclude OEMs from selling a new item every single time, and expect commercial opposition in this regard. However with increasing pressure on the cost of healthcare and additional focus on environmental concerns, sustainability initiatives are a cornerstone of responsible healthcare behaviour and Stryker believes, that within a validated and effective framework, remanufacturing can offer significant benefits to healthcare within Australia.

Yours sincerely,

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