

**Cook Medical Australia's
comments to the
Consultation Paper:
*Proposed regulatory
changes related to
personalised and 3D printed
medical devices***

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Cook Medical Australia

Cook Medical, based in Bloomington, Indiana, USA, is a privately owned medical device company. Throughout its 54 year history, Cook Medical has pioneered many of the medical devices currently used to perform minimally invasive medical procedures. The company has grown to now serve 13 specialties with over 16,000 products.

Cook Medical's Australian business, Cook Medical Australia, is based in Brisbane and employs more than 500 people in manufacturing, R&D, operational and sales capacities. The Brisbane facility is also Cook Medical's Asia Pacific (APAC) headquarters and provides support for the more than 1,200 staff across the APAC region. As a manufacturer, Cook is one of only a few medical device companies that continue to utilise Australia as a manufacturing base. From this facility, Cook Medical exports Australian made products around the world. Through our R&D function, Cook Medical Australia has grown to become a centre of excellence for the design, development and manufacture of endovascular aortic devices and products designed for use in reproductive health.

Background

As a manufacturer and supplier of custom made devices, Cook Medical welcomes the opportunity to comment on the consultation paper: *Proposed regulatory changes related to personalised and 3D printed medical devices*. Cook Medical manufactures a range of endovascular grafts to treat aneurismal disease of the aorta. Standard registered off-the-shelf products are only able to treat patients who fit the anatomical criteria for which the devices were designed. Consequently, Cook Medical manufactures custom made endovascular grafts for patients whose anatomy or disease progression precludes treatment with standard off-the-shelf grafts and who are deemed ‘not fit enough’ to undergo open surgical repair. When a doctor prescribes a custom made graft for their patient, the doctor’s requirements and the patient’s CT scans are provided to Cook Medical’s Brisbane facility where these grafts are planned and manufactured (not utilising 3D printing). It is assumed that these custom made endovascular grafts will continue to be considered custom made devices under the TGA’s proposed new definition.

Responses to applicable questions

Questions for consideration – Proposal 1

- **Is the proposed definition for custom made device clear enough; or should additional measures be taken such as:**
 - **Should the number of custom made devices that a manufacturer or sponsor can supply in one year be limited? The FDA limits this number to 5 per year in the USA, a country whose population is more than 10 times that of Australia.**

The proposed definition for custom made device is clear and Cook Medical does not see the need for additional measures, such as a set limitation. The proviso that “there is no commercially available alternative medical device” will effectively provide a limitation on supply of custom made devices. Furthermore, a very small arbitrary cap may limit access for patients who require custom made devices.

- **Should the TGA implement an application and approval process for the use of a custom made device? This is the approach taken by Health Canada.**

Cook Medical does not have any concerns with adopting a Health Canada approach (assuming that the approval process by the manufacturer is per type of device and not per individual custom made device). However, if the changes in Proposal 2 are implemented, such as the annual reporting requirement, there is probably little need to adopt this additional process.

- **Do you have any other comments or suggestions about the proposed definitions?**
- **Do you have any other comments or suggestions for alternative or additional strategies?**

It is possible that people not familiar with the TGA definitions could make the false assumption that a “patient specific device” is a custom made device. The TGA could employ some strategies to draw attention to the definitions e.g. clearly highlighting the definitions in guidance documents / education materials etc. International definition alignment would also be helpful.

Questions for consideration – Proposal 2

- **Are there any issues or unintended consequences that may arise out of these proposed changes to the custom made conformity assessment procedure?**
- **If there are issues, can you provide suggestions for addressing them?**
- **Do you have any other comments or suggestions for alternative or additional strategies?**

Cook Medical is supportive of the changes to the custom made conformity assessment procedures. Alignment with existing European regulations should not cause any significant issues.