OMX SOLUTIONS

TGA Consultation Paper. March 2019

OMX-Solutions Overview:

OMX Solutions is a four-year-old truly 21st century company, born of the digital age. We supply innovative, print-to-order, bespoke patient specific 3D Printed medical devices for the specialized area of craniomaxillofacial surgery. As a start-up company, we have the flexibility of providing custom devices which can easily and rapidly be delivered using CAD-CAM and additive printing technology. With our experience in digital design, and our successful use of devices developed by advanced additive & subtractive manufacturing methods, we have the capability of producing an unlimited range of medical devices that is only limited by our imagination and the patient/surgeon specific requirements.

Since the company's inception in January 2016 our aim is to become the world leader in the development of exciting new surgical concepts, products and devices that will revolutionize Craniomaxillofacial surgery. To date, OMX Solutions has complied with and conformed with all required regulatory requirements for the manufactured implants and have the TMJ, Bio models, Splints and Surgical Guides registered.

OMX Solutions currently employees ten (10) people into its business. Six (6) of these are engineers and further to the total an additional three (3) engineering interns will commence work with us in 2019.

OMX-Solutions appreciates the opportunity to provide some comments to address the proposed changes to current medical regulatory framework around custom and personalized medical devices. The current provisions for Australian manufacturers exempt them from being included on the ARTG and this is largely because personalized devices are not commercially available from "mass manufactured" product lines. We understand that the TGA has concerns around the increased development of digital, 3D technology and the development of new implants and devices.

In preparing my response I reviewed my previous document submitted on this matter in December 2017. In my view there would seem to be some repetition in the nature of the discussions and points to be covered. I remain curious that this is to be covered again and that from my position little if any value or weight has been placed on previous submissions and a point, I have had concurred within industry and other stakeholders. I note again that in several sections of the paper it is implied that there is no or little regulation of customized implants and which I would contend is simply not true. The current requirements for customized implant regulation states:

Manufacturing of custom-made devices must at a minimum, meet conformity assessment procedures regulated by the TGA. These include conformity assessment procedures prescribed under Part 7, Schedule 3 of the Regulations that comply with the relevant Essential Principles in Schedule 1 of the Regulations.

Custom made devices are not required to undergo premarket assessment by the TGA or to be included on the ARTG before supply.

The current outline of the Essentially Principles is a comprehensive format of requirements to ensure safe products and equipment. A review of its sections makes clear that this is a conformity requirement for much more complex and higher risk products than those for orthotics, eye wear and the like as contended, and which are well applied to custom products and custom implants. It is also my understanding that this exemption for custom devices was not limited to those that are often referred to in the discussion paper, namely orthotics and eyewear.

By reviewing the guidelines, and consulting medical stakeholders in consumer, health professional, laboratory professional and research capacities, it is OMX-Solutions understanding that the TGA hopes to "potentially re-define 'custom-made devices'" and clarify the terms of certification where high risk 3D printed medical devices are concerned. OMX-Solutions believes that the current requirements of essential principles are a good system and one which could be improved on and broadened in its application to other devices, manufacturers and products as opposed to enforcing the requirements for a full TGA certified process as per mass produced products.

At the heart of the issue for companies such as OMX-Solutions is that the devices we are creating and manufacturing are fully customized, patient specific, designed with clinician input and utilizing wherever possible proven and reliable parameters to address unique, deformed and clinically challenging anatomy where few if any other viable solutions are available or practical.

To the extent that premarket assessments may be required for unique customized implants presents an impossibility for any business and the grounds of viability. Because each implant is unique and so has significant differences from one implant to another and the design and creation of each implant is not to a standard template, and dependent upon the digital images and clinical indications (and clinician requirements in some cases), the premarket assessment of every implant is simply not possible.

Fully customized implants for all intense purposes may not have any similarity to conventionally-manufactured implants and so the same regulatory oversight and requirements to customized implants needs to be and has to be different.

Further the "General Principles" as outlined for Medical Devices Essentially Principles Checklist pages 1-3 make clear the robust level of safety conformity and attention to compliance.

Use of medical devices not to compromise health and safety

A medical device is to be designed and produced in a way that ensures that: (a) the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user of any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and (b) any risks associated with the use of the device are: (i) acceptable risks when weighed against the intended benefit to the patient; and (ii) compatible with a high level of protection of health and safety.

Design and construction of medical devices to conform with safety principles

(1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art. (2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must: (a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and (b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and (c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and (d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted. (3) In paragraph 2 (d):

residual risk, for a medical device, means the risk remaining after the measures described in paragraphs (2) (a), (b) and (c) have been applied.

Medical devices to be suitable for intended purpose

A medical device must: (a) perform in the way intended by the manufacturer; and (b) be designed, produced and packaged in a way that ensures that it is suitable for one or more of the purposes mentioned in the definition of medical device in subsection 41BD(1) of the Act.

Long-term safety

A medical device must be designed and produced in a way that ensures that if: (a) the device is used within the period, indicated by the manufacturer, in which the device can be safely used; and (b) the device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and (c) the device is regularly maintained and calibrated in accordance with the manufacturer's instructions; the characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected.

Medical devices not to be adversely affected by transport or storage

A medical device must be designed, produced and packed in a way that ensures that the characteristics and performance of the device when it is being used for its intended purpose will not be adversely affected during transport and storage that is carried out taking account of the instructions and information provided by the manufacturer.

Benefits of medical devices to outweigh any undesirable effects

The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable effects arising from its use.

In the discussion paper the TGA have outlined six (6) proposals for regulatory change. OMX-Solutions will only make comment on the five, as we have no business or experience in the area of printing human tissue and materials. We will endeavour to provide, in brief, our reasonable views on the key areas that we identified from the consultation paper and seek to become a noted and experienced stake holder for future and any further discussions in this area.

Proposal 1: New Definitions for Personalised Devices:

OMX-Solutions Response:

We have no issue with the definitions. What is more important is implications and intended actions and rules to be applied to the new definitions for manufacturers.

Whilst we agree fully with the premise that like conventionally manufactured mass-produced medical devices, 3D printed mass-produced medical devices are not custom-made devices, we would suggest that with reference to the discussion paper from 2017:

"A proposal for consideration is to make the definition of custom-made device more specific so that it is clear that custom made devices are not intended to be manufactured through a routine process on a commercial scale but instead are for cases involving rare patient conditions or anatomy where there is no commercially available alternative."

I have used this reference point from the 2017 paper as there is little actual discussion or suggestion offered in the new document and so assume that this would be a continued theme? The intent for the review of definitions should be to allow an appropriate categorization and treatment of devices to ensure a safe and acceptable outcome for patients and the development of standards for ongoing improvement and achievement in this developing area. We would contend that perhaps a custom device should not be limited by rare or commercial conditions as this limitation has little to do with the safety or efficacy of a device or its construction and raises a raft of contentious issues around further definitions such as;

- What is rare and who deems it to be so
- What is commercial and who deems it to be so

OMX would suggest that there are great many applications beyond these limited two categories that would benefit now and into the future from custom devices and implants and to narrowly apply only set cases as applicable is to perhaps set up a system for failure and short coming – and indeed partly why we suspect this review is happening.

A great many of the OMX-Solutions implants are designed to address unusual patient anatomy, to avoid patient vital structures, to conform precisely to bone and other anatomical structures and to offer surgeons the opportunity to have a reliable and predicable solution for their patients where bone anatomy is small, surgical access is restricted and stock is limited (none of which are necessarily rare).

OMX-Solutions suggest that a far more accurate measure for customization would be to understand and appreciate the start to finish processes and work stages to create a customized device.

Our additional comments are more directed to the TGA intended actions and requirements that would be applied to the manufacturers and not the definitions per sae. These would include:

- As mentioned, who would deem a device custom and on what grounds specifically based around rare and commercial considerations. Additionally, what recourse to

review would this system have and how it would it address the next disruption to manufacture

- The more adapt and busy an enterprise, the more experienced and proficient they should become. The opportunity for business to develop and support their manufacturing and utilizing the essential principles as their standards would seem important to us in ensuring trusted, competent and certified businesses undertake custom work – not organizations on an ad-hoc basis with regards to safety and quality.
- The cost in time and expert personnel to create and design custom products is considerable and even if starting from known parameters and templates of sorts. There will be an ongoing surgical desire to continue to use custom implants and particularly in challenging and difficult surgical anatomies and even if this anatomy is not abnormal. The engagement of clinicians and expert designers/engineers to create custom devices is but a part of the collaborative nature of device manufacture to ensure reliable and safe devices.
- OMX-Solutions and others in this industry work in too small a market to be viable for mass produced devices and with patients requiring treatment now. It is a concern for us what additional regulatory requirements beyond strict adherence to the essential principles may mean for these patients in delayed treatments. As part of our development process we work with a wide variety of reference points including available literature, image and patient data, software programs, clinician input, data on file, testing (both simulated/virtual and physical) and findings from previously implanted outcomes all of which form part of our requirements for ISO 13485, technical files and our essential manufacture principles for conformity.

Proposal 2: Changes to the Custom-Made Conformity Assessment Procedure:

The Suggested Changes:

It is proposed to change the conformity assessment procedure for custom made devices to require:

- that the manufacturer's statement about a custom-made device is provided to the patient receiving the device. This is the current requirement in Europe.
- that the TGA be allowed to enter and inspect custom made device manufacturing sites, in accordance with the authority it must inspect all other medical device manufacturers.
- a manufacturer in Australia or sponsor of custom-made devices to provide an annual report to the TGA of the custom-made devices it has supplied.
- documentation about an implantable custom-made device to be maintained for a minimum period of 15 years, the current specification of a 5-year retention period is inadequate.

OMX Response:

My comments to this section are again echoed from previous discussion paper from 2017.

OMX would encourage the highest of standards for all manufacturers in the custom device space. Australia has a unique international opportunity in industry and the healthcare industry to be a global leader in 3D Printing and manufacturing. It is our view as we strive for the relevant global accreditations that the highest of standards prevail across all parts of the manufacturing process and ideally provide a universal passport to access other countries and markets. OMX-Solutions concern with the introduction of mandatory reporting, documentation for patients and routine or random inspections will impose further mandatory requirements on companies, in addition to Quality programs such as ISO level certifications which will only further exacerbate costs and seriously impede ongoing business.

We are uncertain to the desired outcomes and intentions, that we adopt the European model with respect to the health professional assuming responsibility or to provide the patient with a statement/document would likely achieve? We do know it will introduce further paper work with questionable value. If the devices are manufactured according to the required regulatory levels – then one must ask why would additional checks and balances be required? Additionally, this could introduce further delays to manufacture and patient surgery times – in our view un-necessary.

Further, if the custom devices are made to the required standards and essential principles why the need for documentation and which is not required for any other device? Additional questions on this include:

- what happens if the surgeon loses, forgets or does not provide the document? The patients are under the care of the surgeon in our work and the company has no interaction with the patient and so cannot be held responsible for patient specific documents and their receipt
- who will monitor this process and ensure the transactions of documents to patients occurs and how will it be enforced and made compliant?
- We remain unclear of the intention and benefit for this document transaction for any party and one ought to note again that the patient is in the care of the surgeon

and his choice of surgery, approach, hospital and implants are all largely an arrangement, and consented to, by patient with consultant clinician.

Keeping documents and files for 15 years as indicated is all fine and possible – but the cost of keeping and maintaining them is not without significant cost and burden and particularly for small companies working in this area. There are few what could be termed "large" companies working in this space in MedTech because by virtue the problems their products are addressing, we are not working in high volume "mass" markets. This is an additional cost and administrative burden that will weigh on business viability.

OMX-Solutions would like more information on two of the suggested changes;

If an annual report is required, what specifically would be required to be reported? There is little indication of what may be required/requested, timing to submit and so therefore hard to comment beyond, other than that this would be a further impost on business for no net gain by any party.

Also, the right to enter premises whilst in principle should not be an issue, without details around for what purposes, on what notice and for what intentions it would be good to have further understanding for comment. A good understanding around the scope and requirements of any such visit should be clear and communicated as part of any discussion piece if comment is being sought.

Proposal 3: Introduce a framework for regulating medical device production systems – without the need for manufacturing certification:

What would this mean?

This change would allow hospitals and healthcare practitioners to use approved ***medical device production systems*** to produce medical devices of Class IIa and lower for treating their own patients without being required to meet the regulatory requirements of a manufacturer.

OMX-Solutions Response:

OMX-Solutions does not manufacture products that it believes should not in the least meet essential principles and conformity.

We remain unconvinced that there should be exceptions to the "lower risk" products and believe that all medical manufacturers should be covered by the same rules. There is risk in all manufacture and that manufacture should best be left to those that are expert and dependent upon it. The option to have exclusions for products and organizations in our view compromises the integrity of what may be achieved and allow opportunities for a "do-it-yourself" enterprise – in our view.

Proposal 4: Update the classification rule for medical devices that record diagnostic images so that it includes for example 3D printed models and patient anatomy:

What would change?

It is proposed that the existing rule for X-ray film as Class IIa should be changed to the following:

> **5.4 Medical devices intended to record diagnostic images**
>
> A medical device that is intended by the manufacturer to be used to record diagnostic images is classified as Class IIa. This includes software and anatomical models intended for diagnosis or investigation of the anatomy.

What would this mean (From previous 2017 paper)?

Manufacturers of anatomical models would be required to hold appropriate conformity assessment evidence for a Class IIa device. This would not apply to hospitals or healthcare practitioners if they used a ***medical device production system*** to produce the anatomical models for treating their patients, and the ***medical device production system*** was included in the ARTG.

Manufacturers of software that is intended to be used to record patient imaging that will be used for diagnosis or investigation of the anatomy will be required to hold appropriate conformity assessment evidence for a Class IIa device.

Due to changing technology for patient imaging, and the advent of medical device 3D printing, this rule should be updated. Anatomical models that are manufactured by 3D printing of a patient's digital images for consideration by a specialist in diagnosing a condition or planning a surgery, are also medical devices that are used to record diagnostic images (but not necessarily from an X-ray source). It is reasonable to think that these anatomical models should require the same regulatory oversight, to mitigate the risk of inaccuracy, and to ensure they are a true representation of the patient's anatomy with sufficient quality for their diagnostic purpose. Software that records patient diagnostic images should also be captured by this rule.

OMX-Solutions Response:

OMX-Solutions believe that it would seem an unnecessarily high rating for general guides and models. It potentially opens the way for surgeons and hospitals to print their own models from the patient films and without the restrictions and impost that a Class 2a category may require. To avoid the regulations and costs, this potentially opens the market for poorly constructed and DIY models that may not have the necessary quality and accuracy that a commercial and regulated manufacturer may have and further, by default of an "educational label" introduce further risk and safety issues for surgery and patient outcomes.

What would change is that the availability of models and guides from certified, competent and compliant manufacturers very likely would be reduced. The movement of these relatively inexpensive items (and which require significant software, data interpretation, infrastructure and materials to create) to a class 2b and, all of the additional regulatory requirements that this would introduce would likely result in many companies (OMX-Solutions included) evaluating the viability of this type of product offering. Commercial mass production would be unlikely to pick up on this product category with a change of Class due to the labour and expertise required to manufacture and the niche product requests that are usually associated with models when ordered.

The relative costs and materials involved currently in the manufacture of these devices and guides as either disposable instruments or items to assist surgery would very likely make these very useful tools less accessible. Acknowledging that their accuracy is very important and that by virtue of a measurement piece that they would (if mass produced) be a class 2a, does not address the fact that every bio model and guide will be different on a very large number of fronts.

It would be our view that adherence to the essential principles would be a means of ensuring quality and accuracy and given that a change in classification will not necessarily change the manufacturing or realistically be able to test/measure the final products. It should also be noted that as part of the current Essential Principals, the measurement aspect and requirement is covered as part of section ten (10) and with three (3) key assessment pieces. Further we would be curious to know how re-classifying the models to 2b will alter the capability of any regulatory body to assess compliance with respect to the

accuracy, shape, angle and other key structural features of any anatomical model without significant computer software and designing capabilities in a virtual environment. Every model will be different, and it is the quality of all parts of the process from scan to part creation that is important (Essential Principals) and not the classification that should be the overarching concern for safety and quality.

OMX-Solutions remain unsure and unconvinced that re-classification of the software programs that are currently used for much of the manufacturing process will achieve any advances in the safety and risk reduction aspects of the processes. Much of the software is either proprietary or engineered as proprietary by the organization. We are not certain with what vigour and capability that this could be addressed as part of a certification process and in some cases how the software would be regulated – especially if it is a proprietary or even a commercially available CAD-CAM program? OMX-Solutions would need to know much more detail around the intentions in this area of our design and engineering business to be comfortable with any changes to classes and new regulatory requirements. Again, I would emphasize that part of the key underlying foundation of quality for products from this emerging area is the Essentially Principles of Manufacture.

Proposal 6: modifications and adaptions to personalize a medical device must have been intended by the original manufacturer of the device:

What would change?

Additional text will be added to the regulatory framework to ensure that it is clear that a person will not be considered a manufacturer in circumstances where a medical device has been assembled or adapted for an individual patient and the assembly or adaptation is in accordance with validated instructions provided by the manufacturer of the relevant device. However, if an

individual modifies or adapts a device which has already been placed on the market or put into service in such a way that compliance with the essential principles may be affected, that person shall assume the obligations incumbent on manufacturers and will be subject to the compliance and enforcement regime on that basis.

The need for the provision of validated instructions by the original manufacturer will also be reinforced.

What would this mean?

The effect of these changes will be to clarify the circumstances in which an entity holds responsibilities as a medical device manufacturer.

OMX-Solutions Response:

We have no issue with the suggested proposal from the limited examples in dental resins. We would like however to understand this further with more relevant examples of how this change would be applied to medical devices in the opinion of the TGA. OMX-Solutions requests further detail and examples to support our reserved endorsement for this change and implications for our business specifically.

Summary:

The discussion paper suggests that the key benefits of the proposed changes are:

The proposed regulatory changes are intended to align with the objectives for regulating personalised medical devices, including 3D-printed devices, which are:

1. minimising public health and safety risks
2. maintaining consumer confidence in the regulation of medical devices
3. aligning, as far as possible, with international best practice, and

4. minimising unnecessary regulatory burden.

OMX Reply:

- We do not believe that there is a clear and identified means that by adding the additional regulatory requirements will deliver any increase in public health and safety. The suggestion implies that the current requirements around Essential Manufacturing Principles and other rigorous quality and manufacturing principles is ineffective – which OMX-Solutions cannot agree.
- Maintaining consumer confidence is interesting and I was not aware that there was a diminished level. We are not convinced that increased regulation in a very small and niche area for non-mass market devices is the vehicle to drive this goal.
- Alignment to international markets is desirable and provided that regulatory access to these markets is also aligned. IT is not satisfactory for Australian manufacturers to continue to meet or exceed international regulatory criteria in Australia to only have to repeat process and applications for access to these markets. A first world health economy/market passport is highly desirable and one which includes more countries than those in the current IMDRF framework.
- OMX-Solutions fails to appreciate how regulatory burden can be minimized when more requirements are being suggested and mandated. To minimize would require two old requirements/regulations be removed before a new one could be added.

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OMX-Solutions

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