IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Definitions for Personalized Medical Devices

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

1.0 Introduction

The purpose of this IMDRF guidance is to establish harmonized definitions that are used to describe medical devices that are intended for a particular individual. The adoption of consistent, harmonized definitions for such medical devices could underpin a harmonized regulatory approach for controls on these devices and offer significant benefits to the manufacturer, user, patient, and to Regulatory Authorities. Eliminating differences between jurisdictions supports global convergence and decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

Technology has progressed from the time the original GHTF foundation documents were published. It is now possible to produce medical devices that are individualized, for example, using additive manufacturing (3D printing) methods based on patient CT scans, on a commercial rather than artisanal scale. The original GHTF documentation does not adequately address devices of this nature.

Many jurisdictions already define the term custom-made device and have introduced exemption provisions for regulating custom-made medical devices with the intention to cover special cases where commercially available mass produced products are inadequate for the needs and requirements of a particular patient. In some jurisdictions, the exemption provisions were based on the premise that affected devices would largely comprise low risk products or limited use of higher risk implantable devices. In other jurisdictions the exemption provisions were established with the intention that numbers of custom-made devices would necessarily be small, due to the requirement for them to be used only in special cases.

Now regulators are faced with a very different environment. Technology has made “custom-made” devices, including implantable devices for particular patients, within reach on a much greater scale. Consequently, some jurisdictions are noticing inappropriate use of custom-made device exemptions; with growing numbers of patients receiving higher risk classification medical devices to meet their particular needs, under these exemptions.

2.0 Scope

This document applies to all medical devices, and is intended to identify and describe different categories of devices that are produced for the use of a particular individual, and also to define some other terms that are relevant to defining these types of devices.

3.0 References

GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices*

GHTF/SG1/N78:2012 *Principles of Conformity Assessment for Medical Devices.*

GHTF/SG1/N70:2011 *Label and Instructions for Use for Medical Devices.*

GHTF/SG1/N071:2012 *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*

GHTF/SC/N4:2012 *Glossary and definition of terms used in GHTF documents*

IMDRF/SaMD WG/ N10 FINAL:2013 *Software as a medical device (SaMD): Key Definitions*

ISO/ASTM 52900:2015 *Additive manufacturing — General principles — Terminology*

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

USFDA CDRH, Technical Considerations for Additive Manufactured Devices - Guidance for Industry and Food and Drug Administration Staff, 5 Dec 2017

USFDA CDRH, Custom Device Exemption - Guidance for Industry and Food and Drug Administration Staff, 24 Sept 2014

4.0 Definitions

4.1 **personalized medical device –** a generic term to describe any of the types of devices that are intended for a particular individual, which could be either a **custom-made**, or **adaptable**, or **patient-specific** medical device.

4.2 **custom-made medical device –** a medical device that, at a minimum, meets the following requirements:

- it is intended for the sole use of a particular individual; and
- it is specifically made in accordance with a written request of an authorized healthcare professional, which gives, under their responsibility, specific design characteristics; and
- it is intended to address the specific anatomo-physiological features or pathological condition of the individual for whom it is intended.

Note 1: **patient-specific medical devices, adaptable medical devices** and **mass-produced** medical devices made by means of industrial manufacturing processes in accordance with the written request of an authorized healthcare provider, shall not be considered to be custom-made.

Note 2: 'Specific design characteristics' means unique design specifications that are based on an individual's specific anatomo-physiological features or pathological condition, and that cannot be proposed by a manufacturer without the involvement of a healthcare professional during the conception phase. (For example, transmitting only dimensions/geometric parameters (such as DICOM files from CT scans) to a manufacturer prior to the production of a medical device is not sufficient to be considered as giving specific design characteristics.)

4.3 patient-specific or patient-matched medical device – a medical device produced by a manufacturer based on a standard device template model, or specified design envelope (e.g., minimum and maximum dimensions, mechanical performance limits, and other clinically relevant factors), that is matched to a patient's anatomy using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging, and which is produced through a process that is capable of being validated.

4.4 adaptable medical device – a mass-produced medical device that must be adapted or assembled at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's specific anatomo-physiologic features prior to use.

4.5 mass-produced medical devices –identical medical devices that are produced in continuous production runs or homogenous batches**.**

Note: A batch is considered homogeneous when equivalent parts or materials are manufactured and/or tested in the same manner, without interruption, typically on the same day or in the same time period, and produced by the same person, or with the same machine/equipment set-up and fulfill the same specifications [Ref *MEDDEV* 2.5/6 Rev. 1 http://ec.europa.eu/DocsRoom/documents/10287/attachments/1/translations].

Appendix

Appendix – Examples of personalized devices

Custom-made medical devices

- An orthopedic implant requested by an orthopedist that, in addition to DICOM files, sends to a 3D printing implant manufacturer specific requirements for rigidity/flexibility that the implant must present in specific locations, due to the unique pathology/condition of the patient.

- Artificial cervical disc replacement, with features specified by a spinal surgeon, for reconstruction of the cervical disc following cervical discectomy to treat cervical radiculopathy in a 7’2” male patient. In this scenario, the osseous dimensions of this patient's cervical spine exceed those which an available artificial cervical disc would accommodate.

Patient-specific medical devices

- Cutting guides used in procedures such as knee arthroplasties, or guides used for pedicle screw placement, that are made by 3D printing based on MR or CT data to match a specific patient.

- Plates used to fix a broken bone, which are made by 3D printing, based on a template model and DICOM files/ images of the patient. The plates are printed within the validated dimensional ranges allowed by the specified design envelope.

- Prostheses produced by a 3D printing manufacturer, from a template model and DICOM files transmitted by an authorized person

- Acetabular guide designed to assist a surgeon with pre-operatively planned placement of the acetabular cup component of a total hip replacement. Under a surgeon’s guidance, the guide may be based upon MR or CT images of a patient’s specific anatomy and pre-operatively planned placement of the acetabular cup. The device, as well as the pre-operative planning process upon which the design of the patient-specific guide is based, is validated within a certain range of anatomical parameters.

Adaptable medical devices

- Thoracolumbar pedicle screw system, which consists of multiple components from a single manufacturer, that allows the surgeon to build an implant system to fit the patient’s anatomical and physiological requirements in accordance with instructions provided by the manufacturer. This assembly may consist of a combination of hooks, screws, longitudinal members (e.g., plates, rods, plate/rod combinations), transverse or cross connectors, and interconnection mechanisms (e.g., rod-to-rod connectors, offset

connectors). Additionally, longitudinal members may require intraoperative contouring, as intended by the manufacturer, in order to fit the individual patient's spinal curvature.

- Mass-produced polymer surgical implants for cranial reconstruction that are supplied sterile and are intended to be thermoformed during the surgical procedure. The instructions for use provide details for heating and shaping the implant to suit a patient's particular anatomy.

- Mandibular advancement orthosis against snoring and apnea, which is adapted to the dentition through thermoforming, and is adjusted by the patient.