IMDRF International Medical Device Regulators Forum

New Work Item Proposal

Definitions for Patient-Specific, Customized and Custom-made Medical Devices

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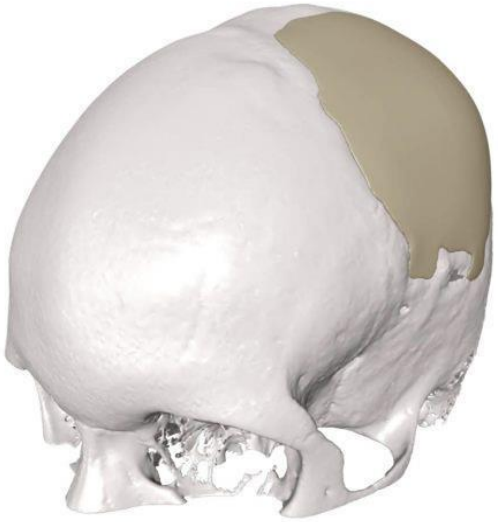
Purpose

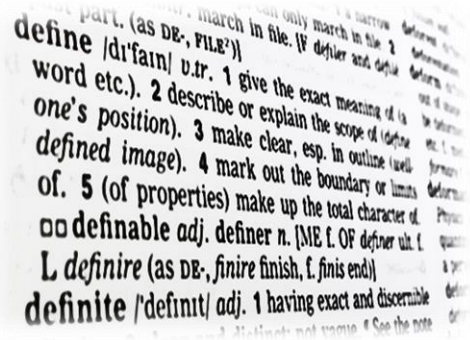
- Develop IMDRF Technical Document that provides recommendations supporting a harmonized approach to defining medical devices that are manufactured for individual patients.



Rationale

- Technology has progressed to where it's now possible to 'mass produce' individualized medical devices:
  - e.g. 3D printing of devices based on patient CT Scan data.
- Original GHTF documentation does not adequately address this type of device.
- Given individual jurisdictions are developing their own approaches to this, there is a risk of international divergence.

Proposed scope


define /dɪ'faɪn/ v.tr. 1 give the exact meaning of (a word etc.). 2 describe or explain the scope of (one's position). 3 make clear, esp. in outline (a well-defined image). 4 mark out the boundary or limits of. 5 (of properties) make up the total character of. □□ definable adj. definer n. [ME f. OF definer ult. f. L definire (as DE-, finire finish, f. finis end)]
definite /'definɪt/ adj. 1 having exact and discernible

- Address the differences between custom-made, customized, and patient specific medical devices
  - Provide definitions for each.
- Address medical devices that are manufactured in a repeatable manner (apart from patient dimensions), especially those produced via additive manufacturing.
- Consider devices that are intended by the original manufacturer to be modified to suit an individual after the device is supplied.
- Recognize that some medical devices are produced in a unique manner, and should continue to be eligible for existing custom-made exemptions.

Benefits

- Address an emerging trend towards personalized treatments in the medical devices sector.
- A common understanding of definitions for these types of medical devices will:
  - lead to harmonisation of requirements for safety, performance and manufacturing of these products; and
  - ensure an appropriate level of regulatory oversight is undertaken.
- Industry stakeholders will benefit from consistent and transparent requirements across multiple jurisdictions.
- Aligns with IMDRF Strategic Priorities.

Previous work / sources of expertise

- Some jurisdictions have already developed relevant guidance and/or changes in regulatory requirements:
  - Custom Device Exemption - Guidance for Industry and Food and Drug Administration Staff - **USFDA** CDRH (24 Oct 2014).
  - Technical Considerations for Additive Manufactured Devices - Draft Guidance for Industry and Food and Drug Administration Staff - **USFDA** CDRH (8 Aug 2016).
  - Regulation (**EU**) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

- Sources of necessary expertise:
  - Experts in premarket regulatory review process
- Proposed Working Group Chair:
  - Dr Elizabeth McGrath, TGA, Australia

Proposed work plan

- Review GHTF foundation documents for references to custom-made devices.
- Review relevant guidance from member jurisdictions that address custom-made and/or patient specific devices.
- Develop draft document proposing relevant definitions – *January 2018*
- Public consultation on draft, comments incorporated (where appropriate).
- Final draft presented to Management Committee for consideration and approval – *September 2018*
- If approved, draft becomes new IMDRF document.

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Thank You