IMDRF International Medical Device Regulators Forum

Personalized Medical Devices Working Group Update

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NWIE Purpose

- The goal of this project is to develop an IMDRF Technical Document that will provide recommendations to support a harmonized approach to regulating medical devices that are manufactured for individual patients.

Rationale

- Technology has progressed to where it is 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 these types of devices.

Benefits

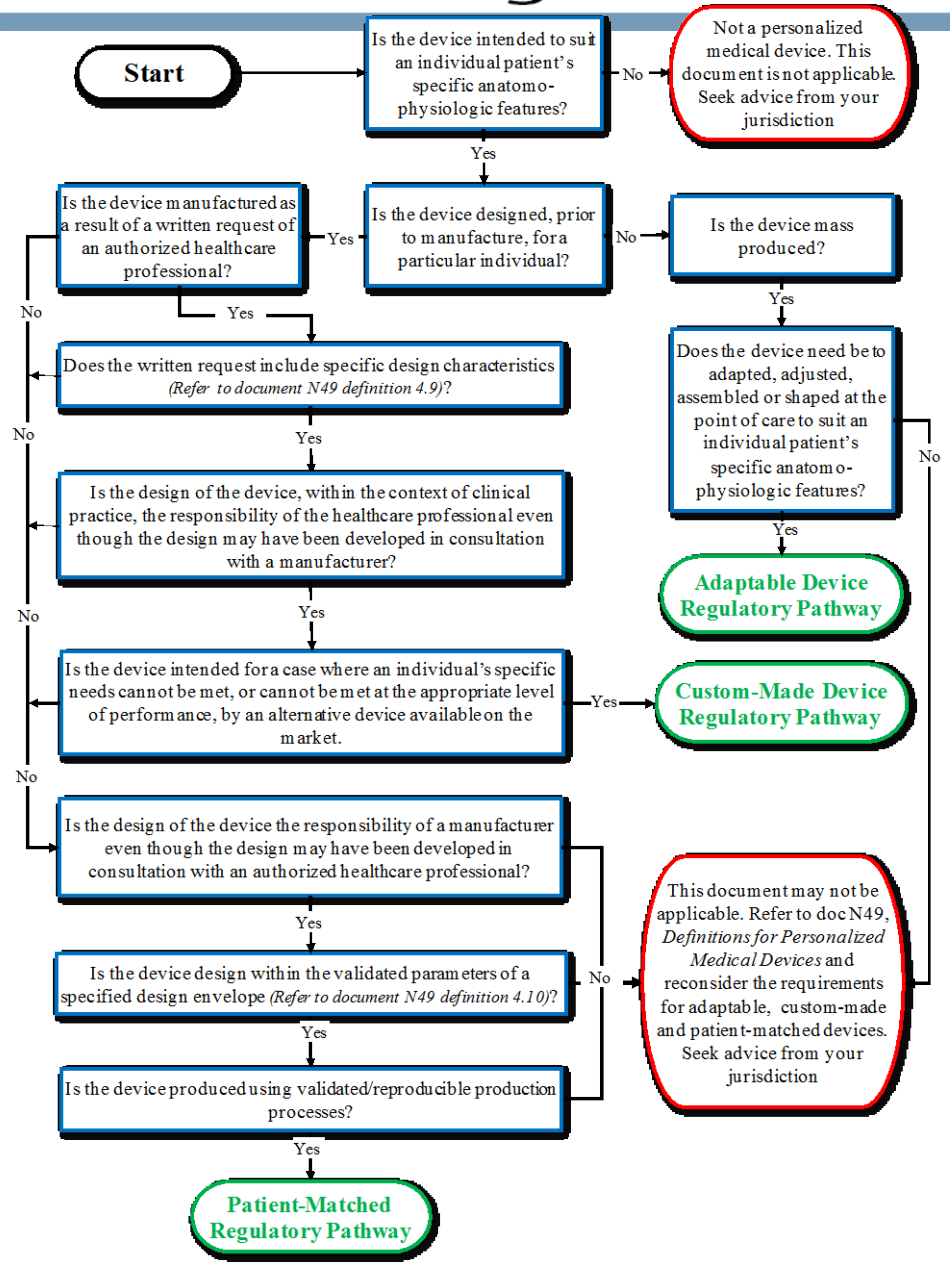
- Addresses an emerging trend towards personalized treatments in the medical devices sector.
- Ensures an appropriate level of regulatory oversight is undertaken
- Leads to harmonisation of requirements for safety, performance and manufacturing of these products
- Provides a basis for consistent and transparent requirements across multiple jurisdictions.
- Aligns with IMDRF Strategic Priorities.

Progress

- Published N49 – Definitions for Personalized Medical Devices – Nov 2018
- Maintained Working Group membership from definitions work – all member jurisdictions represented, also one Affiliate Organization member.
- Built on concepts developed in the definitions document.
- Developed draft document proposing regulatory pathways for the different categories of personalized medical devices.

Features of the Draft Document

Personalized Medical Device Decision Tree



Proposed Regulatory Pathways

Custom-made Medical Devices

- Highest level of detail
- Recognizes unique pathway for custom-made devices

Patient-matched Medical Devices

- Reliance on usual regulatory requirements, according to the device risk classification
- Focus on validation of design envelope

Adaptable Medical Devices

- Reliance on usual regulatory requirements, according to the device risk classification
- Focus on validated instructions for the adaptable features

Proposed Annexes

Annex 1 Considerations for Additive Manufacturing

- Focus on status of raw materials for additive manufacture

Annex 2 Considerations for Point of Care Manufacture

- Introduces concept of medical device production system (MDPS) – collection of goods for producing a particular medical device
- MDPS regulation similar concept to regulation of adaptable medical device
  - Based on the device it is intended to produce
  - Reliance on validated instructions for using the specified system

Next Steps


April/May 2019
Public Consultation
June 2019
Face to Face Meeting to Incorporate Public Comments (Location TBD)
July/August 2019
Teleconferences to Finalize Document
Sept 2019
MC Consideration of Final Document

Thank You