A medical device regulatory roadmap for software

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Background: Today, an estimated 2 million different kinds of medical devices exist in the world market with approximately 150,000 of such devices being used in a single hospital. The burden on healthcare professionals and their ability to operate these devices significantly decreases with the variation in complexity, design and operation methods needed for each device, significantly placing patients care and their lives at risk. Therefore, this project is based on the development of a software device capable of analysing and recognizing medical devices focusing on a specific subsection: the regulatory requirements and compliance processes needed for the successful regulation of software as medical devices in four major world markets: the UK, EU, US and Australia.

Aims: The aim of this project was to analyse current guidelines whilst producing a novel guidance to be used as regulatory roadmaps by manufacturers wanting to place their software medical devices in the market. The primary aim was to develop a new guide that ensured:

1. Manufacturers correctly ascertained whether their software is a medical device or not.
2. Manufacturers correctly ascertain which classification their software sits in.
3. Enable manufacturers to meet the necessary requirements for a medical device.

Methodologies: The design methodology by Peter Ogrodnik was chosen and used in this thesis in order to reach the specified aims.

Results:

Target market	Forms
United Kingdom (UK)	✓ Is it a medical device? ✓ Classification ✓ UK MDR 2002 Requirements ✓ UK Essential Requirements
European Union (EU)	✓ Is it a medical device? ✓ Classification ✓ EU MDR 2017/745 Requirements ✓ General safety and Performance Requirements EU (ANNEX I)
United States (US)	✓ Is it a medical device? ✓ Classification ✓ Code of Federal Regulations (CFR) 21 ✓ General Principles of Software Validation; Final Guidance for Industry and FDA Staff ✓ Policy for Device Software Functions and Mobile Medical Applications
Australia	✓ Is it a medical device? ✓ Classification ✓ Australia TGA Requirements ✓ TGA Essential Principals for medical devices (Schedule 1)

Conclusion: The roadmap developed certifies any manufacturer of medical devices software, regulatory compliance to sell into market. By understanding and addressing the specific requirements of each region, companies will be able to streamline the approval process, reduce time-to-market and most importantly ensure their medical device meets the imperative safety requirements. The proposed compliance roadmap offers a strategic but understandable guide for navigating the complex regulatory environment, ultimately facilitating the global distribution of software medical technologies in healthcare.

Key words: Software; medical devices; regulatory requirements; regulatory compliance; USA; UK; EU and Australia