



Medical Device Innovations: Welcome to the Future

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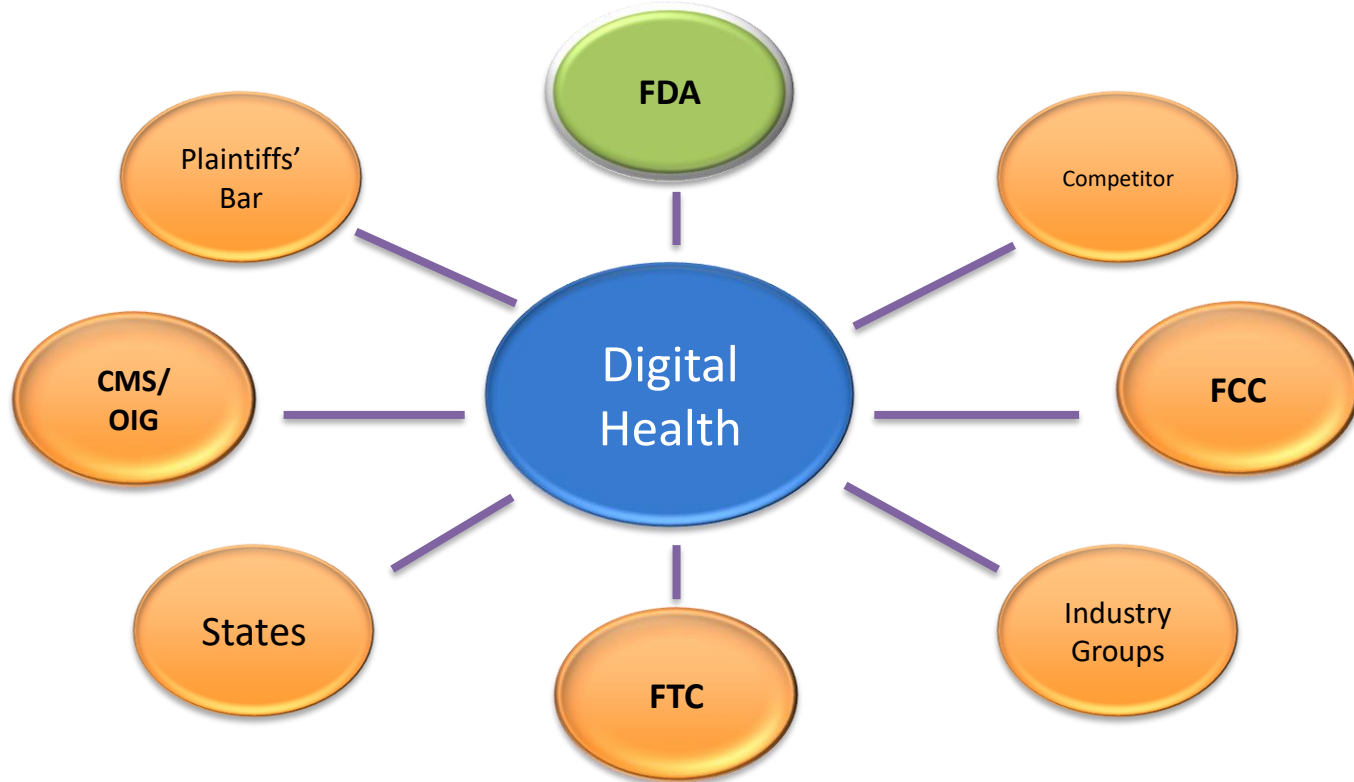
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Overview

- The convergence of wireless and medical technologies is changing the way consumers and healthcare providers manage health and treat disease
- Traditional biotech, pharmaceutical, and medical device manufacturers are partnering with digital health developers to develop products that provide greater flexibility, connectivity, and information to patients, providers and caregivers
- Many of these products and solutions are regulated by FDA and others. However, they present new legal and regulatory challenges for industry and regulators

Potential Regulators



Case Study – Big Device Co.

- **Big Device Co.** manufactures robotic systems with integrated light and micro videoscopes that can perform operations with greater precision and/or more sophisticated movements than a surgeon (*e.g.*, smaller incisions and movements, greater magnification, angles of approach)
- The robotic systems are currently cleared as Class II medical devices for minimally invasive surgical procedures



Midsized Tech Co.

- **Midsized Tech Co.** markets virtual reality (VR) gaming systems and educational tools that include mobile applications and VR goggles
- Current educational uses for mobile application and hardware include virtual “tours” of the human body that provide detailed anatomical representations of major organs and systems
- The system has become a popular teaching and study tool for students and is used in several medical schools and HCP certification programs
- The software and hardware is not currently regulated as a medical device



Emerging Start-Up Co.

- ***Emerging Start-Up Co.'s*** software works with 3D printers to create anatomical models based on an image
- Software and printer is used in mostly non-medical applications (e.g., printing of toys, games and anatomical models for educational use)



Academic Medical Center

- **Academic Medical Center** has developed an Electronic Health Record (EHR) that contains patient-specific pre-operative and post-operative risk and planning tools to help predict and prevent adverse outcomes for patients based on proprietary risk factors
- Information about individual patients is obtained from individual EHRs and HCP notes and analyzed through a proprietary algorithm that includes adaptive machine learning and artificial intelligence (AI) capabilities
- Academic Medical Center also has federal research grants to study and develop innovative surgical techniques



Issues for Discussion

- What factors and trends are driving development of these technologies?
 - 3D printers and software?
 - Virtual Reality software and hardware?
 - Clinical decision support (CDS) and AI tools?
- Regulatory Status and Challenges Involving these Product Categories?

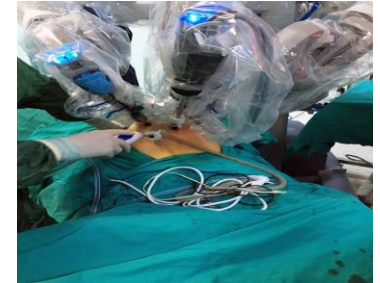
Proposed Partnerships

- Emerging Start-Up Co. wants to partner with Midsize Tech Co. to develop software that integrates Midsize Tech Co.'s VR software and goggles with Emerging Start-up's 3D printing software to create anatomical models of the human heart and surrounding structures
- Emerging Start-Up Co's software will pair with an MRI to view, create and share images of arterial blockages and congenital heart defects in patients, including composite 3D images, that can be rotated or magnified using VR goggles
- The companies wants to market the tool to HCPs for surgical preparation and patient education . Both companies believe the deal will also expand the market for their respective products



Proposed Partnerships Continued

- Big Device Co. wants to partner with Midsize Tech Co. to use the VR technology and images to guide / control surgeries using its robotic systems with greater precision and expand into cardiology applications
- Big Device Co. also wants to partner with Emerging Start-Up Co. to use cardiology anatomical models to prepare for surgery
- Academic Medical Center wants to host pilot program study in which its EHR-based clinical decision support tools will be used to assess both pre-operative and post-operative outcomes for patients who are treated with the integrated surgical tools



Issues for Discussion

- FDA regulatory issues
 - Product approval pathways
 - Does integration heighten regulatory obligations for each component manufacturer?
 - Robotic platform – do the cardiac applications change device class?
 - MRI & 3D printing software – does new intended use transform combined system into Software as a Medical Device (SaMD)?
 - Multi-function devices—evaluate extent to which each component (1) is a device, (2) affects or could affect safety and efficacy of devices within the integrated product or applications

Issues for Discussion

- Safety issues
 - Accuracy of 3D images and anatomical models made from images
 - Limits of anatomical models informing surgical procedures
 - Interaction between MRI and 3D printing software
- Cybersecurity / Interoperability issues
 - Pre-Market: identifying and implementing suitable mitigation strategies
 - Post-Market: robust procedures for identification of risks (*e.g.*, hacking); correction, removal & reporting
 - Testing and validation of combined systems
- Commercial considerations
 - Liabilities
 - Regulatory responsibilities of the parties (reporting, electronic health records, etc.)
 - Establishing quality and compliance systems if components are considered devices (and previously unregulated)