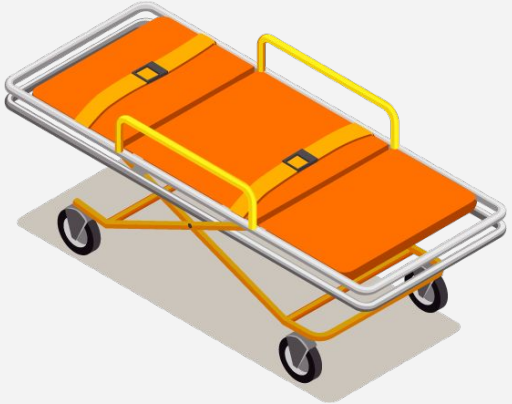
FDA Compliance Checker Gene-Us



Holly Akati, Gabrielle Bruce, Jamie Greenberg,
Kami Ogunyankin, & Haby Thiam

Table of contents

Table of contents

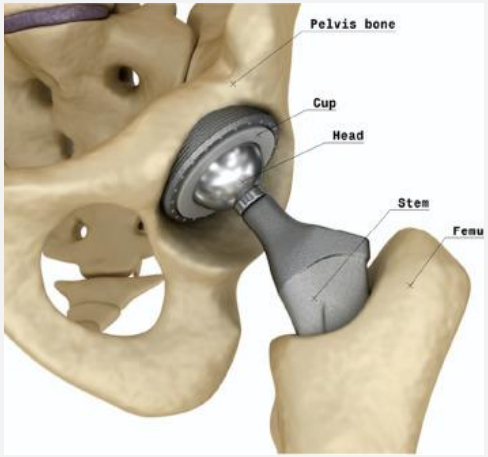
01

Rationale

Automated external Defibrillator

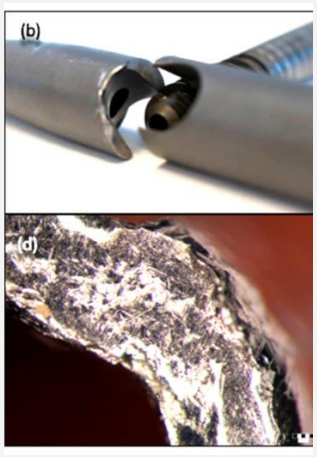
(goodrx.com)

Metal-on-Metal Hip Implant



(sciencedirect.com)

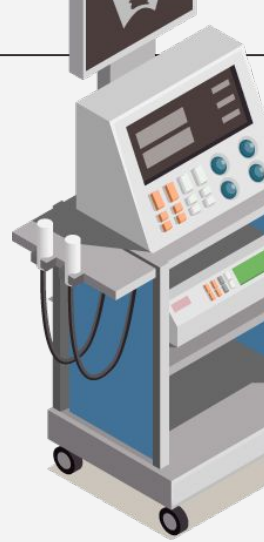
Osteosynthesis Implants



(Nica et al. 2020)

02

Problem Statement

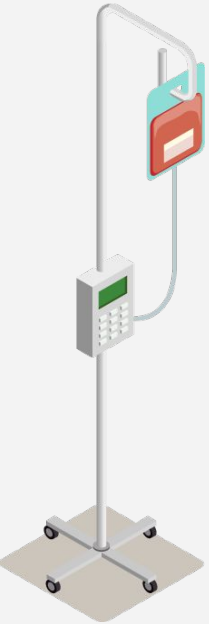


Medical device failures are nothing new to the healthcare and engineering industries. The Food and Drug Administration has recalled many devices due to failures in products like CPAP machines, defibrillators and silicone breast implants to name a few. There were efforts to solve these issues with the 1976 Medical Device Amendments but it resulted in complex processes with many "loopholes". So devices are not being tested thoroughly but instead, held to minimum standards and low quality testing.

(Source: Prof. Victor Krauthamer; GWU Department of Biomedical Engineering)

03

Specifications



Size of Knowledge Database

The final product's database must draw from all aspects of design which are currently approved and tested for medical devices.

Knowledge of Troubleshooting

This product must have an output for any known input, if it is not deemed acceptable according to federal regulations then potential solutions to this error must be given if they are known.

4

Constraints

Deadline

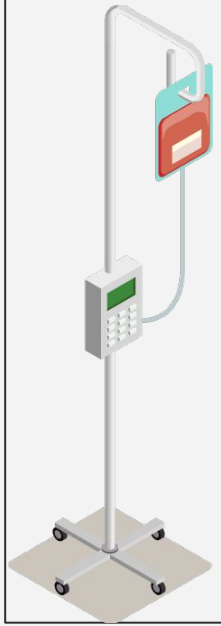
This event is only over the course of two days and the final time deadline occurs at 11:30 a.m. on 02/25/2024

Knowledge

This is an interdisciplinary project where all participants have different majors and must combine their knowledge into one product. Although there are five members there are still some gaps in knowledge that are not covered by any member. An example is lack of software development.

05

Target Market



(fda.gov)

Biomedical engineers are the primary developers of new medical devices. They decide their form and function, including their materials and the rate at which they function. Also, they are required to work to follow the legislation which regulates the design of these devices.

06

Current Regulations

Class I devices (subject to General Controls):

- Pose a low risk

Ex. eyeglasses, toothbrushes, Band-Aids, scalpels

Class II devices (General and Special controls):

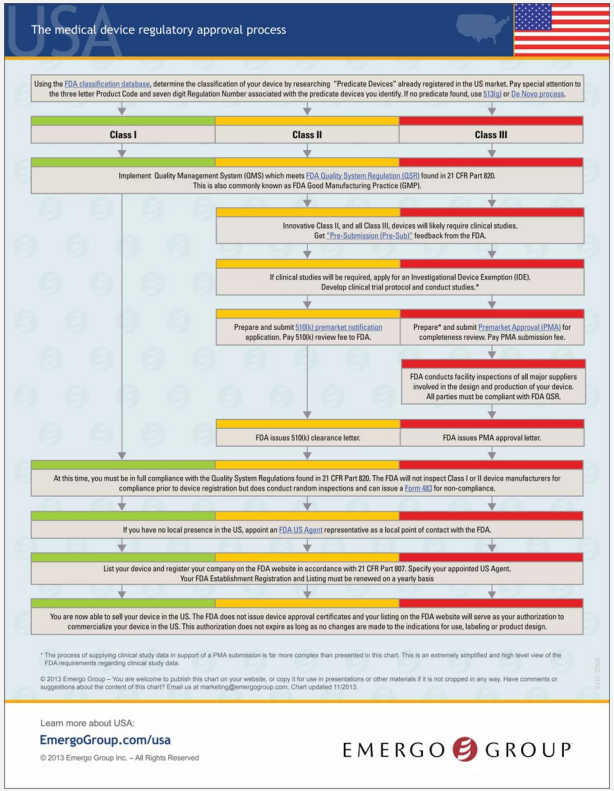
- Pose a moderate risk

Ex. stethoscope, syringes, pregnancy test kits

Class III devices (General Controls and PMA):

- Pose a high risk

Ex. silicone breast implant, catheter, pacemakers



07

Our Product

- We're creating a software system to help biomedical engineers determine if the materials used in their devices are safe and meet industry standards.
- The engineer inputs information about the device, its function, and its component materials. The system checks the materials against databases of hazardous substances and FDA regulations.
- If any hazardous materials are detected, the system denies approval and suggests alternative safer materials. It will also indicates if the materials have been previously tested on people of color and note any side effects to consider.
- The goal is to streamline regulatory compliance and promote the use of ethical and socially responsible materials in biomedical devices.

08

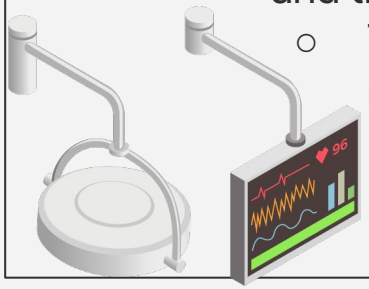
Equity

- Accessible to those around the world
  - Available in multiple languages
  - Free information
- Those in marginalized communities
  - Studies will be done on more people of color and how they affect those of different races/ethnicities
  - Accountability by the public and those in the medical field

09

Applications

- Allergan, known for medical devices and pharmaceuticals, had to recall their Natrelle BIOCELL textured breast implants due to high risk in developing lymphoma
- Main issue with product was the surface texture
  - Allowed for growth of bacteria
  - Higher rates of surface shedding particles in Allergan's implants
- Using our product, Allergan's textured implants would go through system and the materials in them would determine if they should be approved
  - Texture implants would be rejected and would receive alternative materials to use in place of poor materials in product

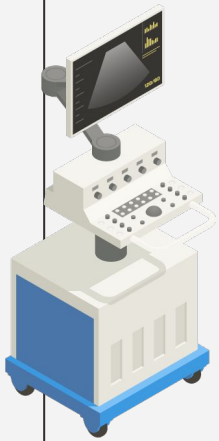


(iStock, 2019)

10

Future Plans

- Sustainability
  - As some materials may no longer be deemed acceptable by the product's standards there should be additional information provided regarding how to safely dispose of these potentially hazardous materials.
- Focus on people of color
  - Studies often lack racial diversity, which is needed since some devices may affect people of different races differently



11

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11

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