Design Report 2

Biomedical Device Design

MECH 4013

Shadman Sakib Rashid

101200114

Automated Chest Compression System

Group members

- Lana Alrayyes
- Jamal Louay
- Angelina Barsoum

Feedback and deficiencies of the design

Members	Feedback
Lana Alrayyes	- More controlled actuation of the pouches for consistent compression - Include battery life capacity - Adding redundant safety systems
Jamal Louay	- Adding a self-checking/self-diagnostic mode to verify system readiness. - Implementing a notification system to keep users updated about the system, like battery life updates
Angelina Barsoum	- Concerns about variability of parameters between patients, like chest compressibility - A one-size-fits-all design may not cover someone with special needs - Need to have variability in force magnitudes and fittings

Proposed changes to design and affected output

1. The issue regarding everyone having different needs in terms of pressure required for compression can be fixed by making changes to how the inflation occurs.
   - In terms of variability of the pressurization, the user can program how much stiff they want the pouch to be or from advice from a physician.

2. In terms of integrating the subsystems more, as suggested, a self-diagnosis feature can be introduced, which will communicate via the user's smartphone and can also talk to medical personnel
3. The mechanics of the design can be improved as supporting structures can be added inside the mechanical housing to regulate the stroke length of the gears.
4. More focus needs to be put into the redundancy of all the related subsystems.

Regulatory (FDA)

Classification: According to the FDA, a device that comes into substantial contact with the patient and can/or/is connected or supporting cardiovascular health is a class 2 medical device as they do have a component of risk attached[1].

The device mentioned in this report meets this criterion, so it is a class 2 medical device.

Moreover, according to the FDA, the product code will be PMJ[2], and it can also be classified as DRM[3. In this case, the DRM code is chosen.
The screenshot is included along with the in-text citation reference of the FDA website where it classes the medical devices.

Fig: PMJ [2]

Device	Compressor, Cardiac, External
Regulation Description	External cardiac compressor.
Regulation Medical Specialty	Cardiovascular
Review Panel	Cardiovascular
Product Code	DRM
Premarket Review	Circulatory Support, Structural and Vascular Devices (DHT2B) Circulatory Support, Structural and Vascular Devices (DHT2B)
Submission Type	510(k)
Regulation Number	870.5200
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Fig: DRM[3]

- DRM Class II is chosen from examples
- Due to this device being used in critical life-threatening situations, it requires a 510K[4] pathway.

Regulatory (Health Canada)

According to the flowchart mentioned here,

Since this device follows rule number 6, it can be classified as a Class II medical device since it contains a gas in the form of a CO_2 canister, and though it is not directly administered, as it is a non-invasive device, it is a Class II medical device.

Conclusion

In terms of FDA classifications,

FDA Code: DMR, Class II, 510K included
Health Canada: Class II

References

[1]https://www.qualio.com/blog/fda-medical-device-classes-differences#what-is-class-2-device

*[2]*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=PMJ

*[3]*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=DRM]

*[4]*https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k