



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	<ul style="list-style-type: none"><li>• More controlled actuation of the pouches for consistent compression</li><li>• Include battery life capacity</li><li>• Adding redundant safety systems</li></ul>
Jamal Louay	<ul style="list-style-type: none"><li>• Adding a self-checking/self-diagnostic mode to verify system readiness.</li><li>• Implementing a notification system to keep users updated about the system, like battery life updates</li></ul>
Angelina Barsoum	<ul style="list-style-type: none"><li>• Concerns about variability of parameters between patients, like chest compressibility</li><li>• A one-size-fits-all design may not cover someone with special needs</li><li>• Need to have variability in force magnitudes and fittings</li></ul>

## 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.

New Search		Back to Search Results
<b>Device</b>	Cpr Aid Feedback Device (No Software)	
<b>Regulation Description</b>	Cardiopulmonary resuscitation (CPR) aid.	
<b>Definition</b>	Provides real-time feedback to the rescuer regarding the quality of CPR being delivered to the victim, and provides either audio and/or visual information to encourage the rescuer to continue the consistent application of effective manual CPR in accordance with current accepted CPR guidelines	
<b>Physical State</b>	An external device generally placed on or near the subject/victim and provides audio and/or visual feedback to the rescuer.	
<b>Technical Method</b>	Mechanical or electro-mechanical. No software.	
<b>Target Area</b>	Chest - skin contact.	
<b>Regulation Medical Specialty</b>	Cardiovascular	
<b>Review Panel</b>	Cardiovascular	
<b>Product Code</b>	PMJ	
<b>Premarket Review</b>	Circulatory Support, Structural and Vascular Devices (DHT2B) Circulatory Support, Structural and Vascular Devices (DHT2B)	
<b>Submission Type</b>	510(K) Exempt	
<b>Regulation Number</b>	<a href="#">870.5210</a>	
<b>Device Class</b>	2	
<b>Total Product Life Cycle (TPLC)</b>	<a href="#">TPLC Product Code Report</a>	
<b>GMP Exempt?</b>	No	
<b>Summary Malfunction Reporting</b>	Eligible	
<small>Note: Class II devices the Food and Drug Administration (FDA) has also published a <a href="#">list of class II (special controls)</a> devices subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (Cures Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet requirements of FDAMA and the Cures Act.</small>		
<b>Implanted Device?</b>	No	
<b>Life-Sustain/Support Device?</b>	No	
<b>Third Party Review</b>	Not Third Party Eligible	

Fig: PMJ [2]

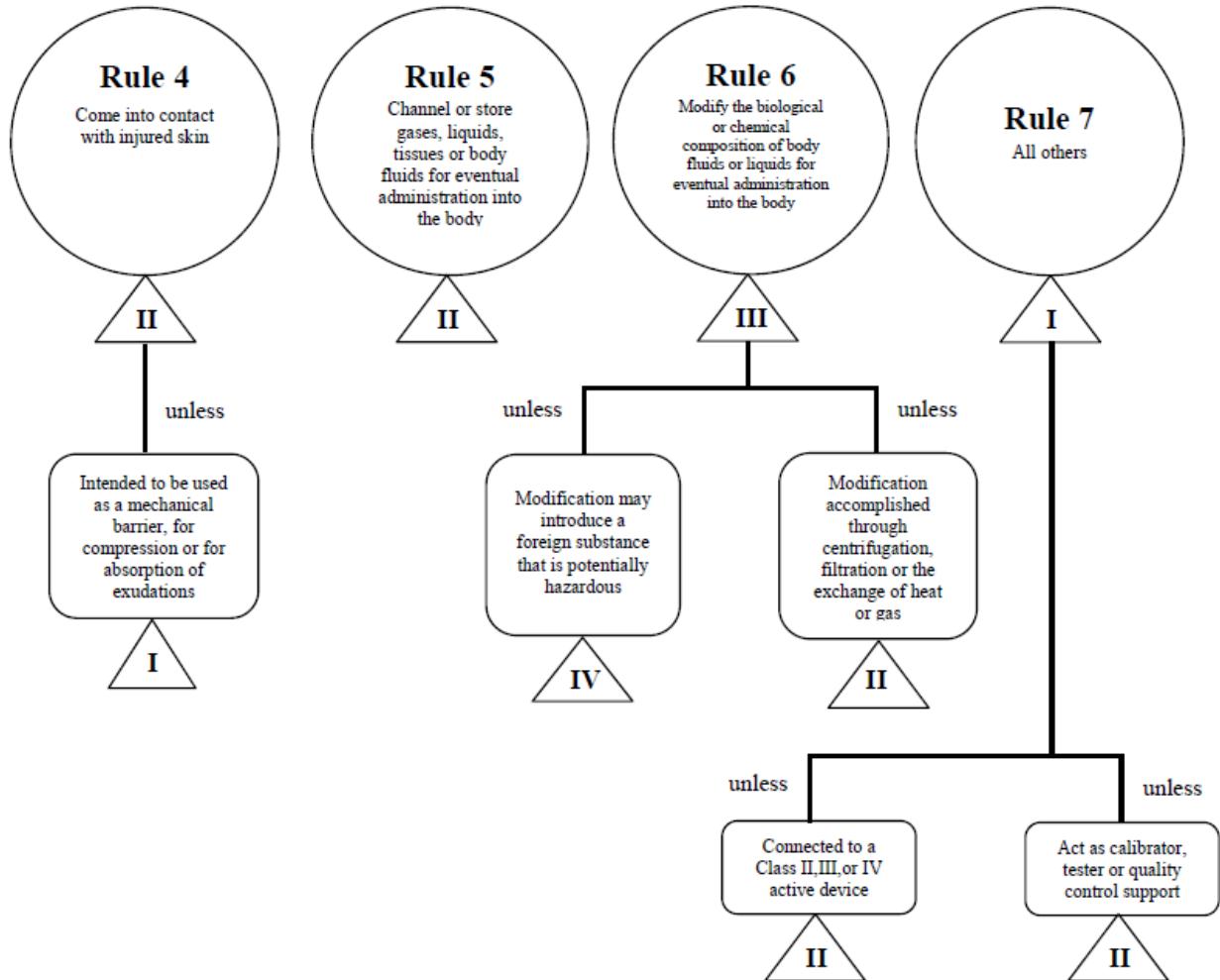
<a href="#">New Search</a>	<a href="#">Back to Search Results</a>
<b>Device</b>	Compressor, Cardiac, External
<b>Regulation Description</b>	External cardiac compressor.
<b>Regulation Medical Specialty</b>	Cardiovascular
<b>Review Panel</b>	Cardiovascular
<b>Product Code</b>	DRM
<b>Premarket Review</b>	<a href="#">Circulatory Support, Structural and Vascular Devices (DHT2B)</a> <a href="#">Circulatory Support, Structural and Vascular Devices (DHT2B)</a>
<b>Submission Type</b>	510(k)
<b>Regulation Number</b>	<a href="#">870.5200</a>
<b>Device Class</b>	2
<b>Total Product Life Cycle (TPLC)</b>	<a href="#">TPLC Product Code Report</a>
<b>GMP Exempt?</b>	No
<b>Summary Malfunction Reporting</b>	Eligible
<b>Implanted Device?</b>	No
<b>Life-Sustain/Support Device?</b>	No
<b>Third Party Review</b>	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<sub>2</sub> 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/cfpcla ssification.cfm?id=PMJ>

[3]<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcla ssification.cfm?id=DRM>

[4]<https://www.fda.gov/medical-devices/premarket-submissions -selecting-and-preparing-correct-submission/premarket-notificat ion-510k>