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BM 2210 - Biomedical Device Design
Feasibility Report: Temperature-Controlled Medicine and Vaccine Cooler Box

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1 Introduction

Vaccines must be maintained within a narrow temperature range (typically 2–8 °C) to remain effective. Current cold-chain solutions are either expensive or unsuitable for low-resource and remote settings. Our project aims to develop a **portable, low-cost, temperature-controlled vaccine carrier** that integrates real-time temperature monitoring, user alerts, and a prototype-level active cooling mechanism using a Peltier module with fan and heat sinks. This feasibility study documents the ideation, screening, testing, and final selection process for the concept.

2 Need Statement

Vaccines must be maintained within their specific required temperature range to remain effective. However, in rural outreach and long-distance transport, the vaccine supply chain is often disrupted without timely detection. There is a clear need for an affordable, portable solution that ensures continuous real-time monitoring of vaccines during transportation.

2.1 Problem

During transportation, healthcare workers often remain unaware if vaccine temperatures fluctuate beyond safe limits. This results in wastage of doses, reduced effectiveness, and potential outbreaks of preventable diseases. The challenge is especially critical in rural and low-resource settings where reliable monitoring systems are limited.

2.2 Existing Solutions

- **Passive vaccine carriers/cold boxes:** Low cost and rugged but provide no real-time temperature feedback and because of the usage of ice packs, the required temperature range is unreliable.
- **Electronic temperature loggers:** Record excursions but only retrospectively; spoilage is often discovered too late.
- **Active compressors or solar-powered cold boxes:** Provide reliable regulation but are expensive, heavy, and unsuitable for last-mile campaigns.

2.3 Proposed Solution

We aim to develop a portable vaccine carrier with built-in digital temperature monitoring, real-time alerts, and an active cooling mechanism. The system will:

- Allow input of the temperature range required for the particular vaccine to be transported via mobile app or dial pad.
- Continuously measure the vaccine's temperature with embedded sensors.
- Send live data to a mobile application and trigger alarms when excursions occur.
- Activate a Peltier-based cooling mechanism with fan and heat sinks to bring the temperature back within the safe range after an excursion is detected.

- Provide automated data logging for compliance and tracking.
- Remain lightweight, affordable, and practical for rural and last-mile vaccine delivery.

This approach directly addresses the limitations of existing solutions by offering a mid-cost, reliable tool for healthcare workers. By reducing vaccine wastage and ensuring safe immunization, it contributes to improved public health outcomes in both local and global contexts.

2.4 Validation

This need was highlighted during discussions with Dr. V. Kayalvili, Director of Trincomalee General Hospital, Sri Lanka. She emphasized that in rural outreach, vaccine transport frequently faces challenges due to inadequate monitoring, leading to potential wastage and compromised immunization.

3 Ideation

A brainstorming session was conducted on 10th September 2025 to generate possible solutions for safe vaccine transport. The initial ideas are summarized in the following ideation diagram.

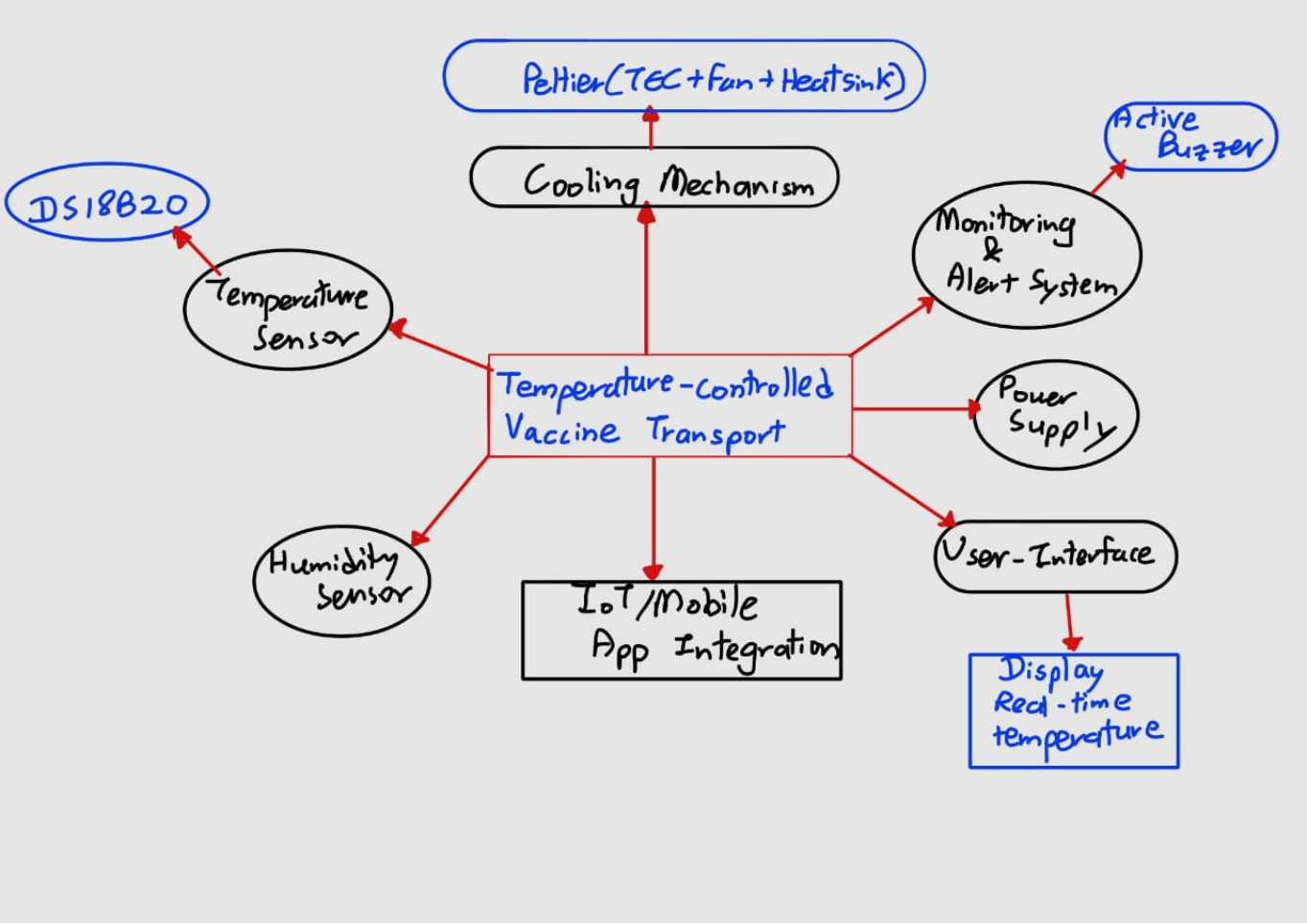

Figure 1: Brainstorm of Ideation

4 Initial Concept Selection

From the above ideation, several possible directions were generated to address the identified need. Ideas that were impractical, too costly, or unsuited to rural deployment were filtered out, leaving us with a smaller set of viable approaches for further consideration.

Cooling Mechanisms: We considered multiple approaches to maintain the vaccine temperature within the required 2–8°C range. Passive cooling using ice packs or phase change materials offers simplicity and low cost but provides no control or real-time adjustment once deployed. Active cooling using a Peltier module with a fan and heat sink was also discussed, as it allows direct electronic control and can be scaled down for a prototype. A hybrid approach that combines passive insulation with active Peltier cooling offers a balance between low cost and controllability.

Monitoring and Alerts: Digital temperature monitoring was identified as a core requirement. Concepts included integrating sensors such as DS18B20 or thermistors to continuously log temperature, display it on an LCD screen, and provide local alerts through buzzer/LEDs. Additionally, mobile app or Bluetooth connectivity was proposed to enable remote notifications, ensuring healthcare workers are aware of any temperature excursions.

Power Supply: Since last-mile transport often lacks reliable electricity, several power supply concepts were considered. Rechargeable Li-ion batteries provide portability, while DC supply is practical for initial prototyping. A solar-powered option was also discussed as a long-term sustainable solution, though cost and efficiency constraints remain challenges at the prototype stage.

User Interface: To ensure usability, the team considered different input and display options. A simple keypad for entering threshold limits and an LCD display for real-time feedback were seen as the most practical choices for the prototype. Mobile app integration was identified as an additional option for future iterations, enabling remote monitoring and data logging.

Affordability and Practicality: Finally, practical considerations guided our initial concept selection. The device must remain lightweight, modular, and affordable to be viable in rural outreach programs. This eliminated bulky compressor-based cooling systems and narrowed the focus toward Peltier-based prototypes combined with smart monitoring and rechargeable power supply.

In summary, the initial concept selection process clustered and refined ideas from the brainstorming session into four main domains: cooling mechanism, monitoring and alerts, power supply, and user interface. These selected directions form the basis of the concepts carried forward into the screening and testing stages.

4.1 Screening Against Need Criteria

The brainstormed ideas were compared against the defined need criteria to evaluate their suitability. Table 1 summarizes the assessment.

Table 1: Screening of concepts against need criteria

Concept	Effectiveness	Portability	Affordability	Reliability	Usability
Passive Cooling (Ice/PCM)	✓	✓	✓	×	✓
Active Cooling (Peltier + Fan)	✓	✓	×	✓	✓
Hybrid (Passive + Peltier)	✓	✓	×	✓	✓
Smart Monitoring (Sensors + Alerts)	✓	✓	✓	✓	✓
IoT / Mobile App Integration	✓	✓	×	✓	×
Battery Power	✓	✓	✓	×	✓
Solar Power Option	✓	×	×	✓	✓

5 Concept Screening

5.1 Intellectual Property (IP)

5.1.1 Temperature Monitoring System

The proposed device includes an integrated temperature sensing system that ensures real-time monitoring of the internal conditions of the vaccine carrier. This feature is essential for maintaining the required temperature range for vaccine storage, preventing spoilage and loss of efficacy.

How it Operates:
Temperature Sensors: High-precision digital temperature sensors are placed inside the vaccine box to continuously measure the internal temperature.

Data Processing: Sensor readings are processed by a microcontroller, which compares the measured temperature against the pre-set safe range for vaccines.

Alert System: If the temperature deviates from the acceptable range, the system immediately notifies the user through audible alarms, visual indicators, or mobile alerts. This ensures timely corrective action.

User interface with keypad input: A simple keypad is provided on the device, enabling users to manually set temperature thresholds.

5.1.2 Cooling Control with Peltier Modules

The cooling mechanism of the device uses thermoelectric (Peltier) modules, which provide a compact and efficient method of active cooling. This ensures the internal environment remains within the required range even in warm external conditions

How it Works: **Peltier Cooling**: Peltier modules generate a cooling effect when an electric current is applied. These modules are strategically installed in the carrier walls.

Heat Dissipation: A heat sink and fan assembly are used on the hot side of the Peltier to efficiently dissipate excess heat.

Automatic Regulation: The microcontroller adjusts the Peltier power based on real-time sensor readings, optimizing energy use and maintaining stable internal temperature

5.1.3 Mobile Application Integration

To enhance usability and provide real-time remote monitoring, the system is integrated with a dedicated mobile application. This ensures that healthcare workers can continuously track and manage vaccine safety even while on the move.

How it Works: **Real-Time Data Display:** The mobile app receives continuous temperature data from the vaccine carrier via Bluetooth/Wi-Fi. The user can view current internal conditions on their smartphone in real time

User Control: Through the app, users can set or modify safe temperature thresholds for different types of vaccines. The system automatically applies these settings for monitoring and regulation

Smart Notifications: If the temperature goes out of the safe range, the app instantly alerts the user through push notifications, vibration, or sound alerts.
Data Logging: Temperature history is stored in the app, enabling record-keeping for regulatory compliance and future reference.

Remote Adjustment: Users can remotely adjust cooling levels and operational settings, ensuring flexibility and reliability in diverse environments.

5.2 Regulation

According to FDA classifications, this device would most likely be considered a low-risk Class I medical device, similar to medical refrigerators and vaccine temperature monitors. Such devices are generally subject only to general controls and are often exempt from premarket notification (510(k)), provided they do not make novel or high-risk claims. For deployment in Sri Lanka, the system must comply with Ministry of Health (MOH) cold-chain policies as well as the World Health Organization Performance, Quality, and Safety (WHO PQS) standards for vaccine carriers and temperature monitoring equipment. Meeting these requirements will be critical for future adoption in immunization programs and international procurement.

6 Business Model

Since Sri Lanka will be the first region of deployment, the business model must align with local healthcare infrastructure, resource availability, and economic conditions. The approach focuses on providing healthcare workers with practical, easy-to-use tools to ensure safe vaccine transport, while leveraging modular design and affordable components.

6.1 Temperature Monitoring Subsystem

Accurate and continuous temperature monitoring is essential to prevent vaccine spoilage. By integrating digital sensors (`DS18B20`) with microcontrollers, the system provides real-time readings accessible via an LCD or mobile app. This subsystem adds value by:

- Reducing human error in temperature tracking.
- Enabling automated data logging for compliance and reporting.
- Offering a modular solution that can be upgraded or replaced independently.

The business model here emphasizes **capital equipment with optional service subscriptions** for maintenance, ensuring reliable sensor performance over time.

6.2 Alert System Subsystem

The alert system, including buzzer, LED indicators, and mobile push notifications, enhances user awareness when temperature excursions occur. This subsystem provides value by:

- Delivering immediate, actionable feedback to healthcare workers.
- Reducing vaccine wastage and mitigating public health risks.
- Complementing existing monitoring systems without major workflow changes.

The business model leverages a **reusable product with low-cost upgrades**, allowing healthcare providers to adopt the alert system as an add-on to existing carriers or as part of the complete package.

6.3 Active Cooling Subsystem (Peltier Module)

The Peltier-based cooling module actively maintains internal temperature within the safe range. Value propositions include:

- Compact, energy-efficient cooling suitable for remote transport.
- Scalable integration with varying carrier sizes.
- Reduced dependency on passive ice packs, enhancing portability.

The business model for this subsystem focuses on **capital equipment sales** with optional local assembly to reduce costs. High-usage units may adopt a **leasing or service model** to cover maintenance of cooling components.

6.4 Power Supply Subsystem

The device's rechargeable Li-ion battery or DC power supply ensures continuous operation in low-resource settings. This subsystem contributes to business value by:

- Allowing flexible deployment in areas without grid access.
- Supporting modular upgrades or replacement of battery packs.
- Ensuring consistent operation of cooling and monitoring subsystems.

The business model incorporates **reusable components with recurring maintenance or battery replacement service**, maintaining sustainability and uptime.

6.5 Mobile Application Integration

The mobile app provides remote monitoring, threshold configuration, and historical data access. Its business value is:

- Enabling centralized data collection for reporting and regulatory compliance.
- Supporting multiple vaccine types with configurable thresholds.
- Offering a platform for future upgrades, including cloud storage and analytics.

The business model relies on a **software subscription model**, with basic functionality included with the device and premium features (cloud analytics, multi-device management) available as optional paid services.

6.6 Summary

By analyzing each subsystem individually, the business model ensures that the temperature-controlled vaccine carrier provides both immediate and long-term value to healthcare workers and institutions. Each subsystem can be scaled, upgraded, or serviced independently, creating a flexible, sustainable, and locally appropriate solution for Sri Lanka's vaccine transport challenges.

7 Concept Testing

7.1 Prototyping

In our proposed solution prototype, we primarily have two main components: the **temperature monitoring and alerting system** and the **active cooling mechanism**.

For the monitoring and alerting subsystem, we plan to use a digital temperature sensor (`DS18B20`) to measure the internal temperature of the carrier. The sensor data will be processed by a microcontroller (ESP32/Arduino), which allows the user to input the desired temperature range through a keypad or mobile interface. If the measured temperature goes outside the defined safe range, the system will trigger a buzzer and LED to provide an immediate alert. An LCD display will also be used to show real-time readings and status messages.

For the cooling subsystem, we intend to use a Peltier thermoelectric module paired with a heat sink and cooling fan. Thermal paste will be applied to improve heat transfer efficiency. When an out-of-range temperature is detected, the microcontroller will automatically activate the Peltier module via a driver circuit (MOSFET or motor driver). This will actively reduce the internal temperature until it stabilizes within the safe range.

The prototype integrates these subsystems into a compact insulated box, powered by a DC supply or rechargeable battery. The block diagram of the proposed prototype architecture is shown in Figure.

7.2 Testing Plan

The prototype will be tested for:

- Sensor accuracy under lab conditions.

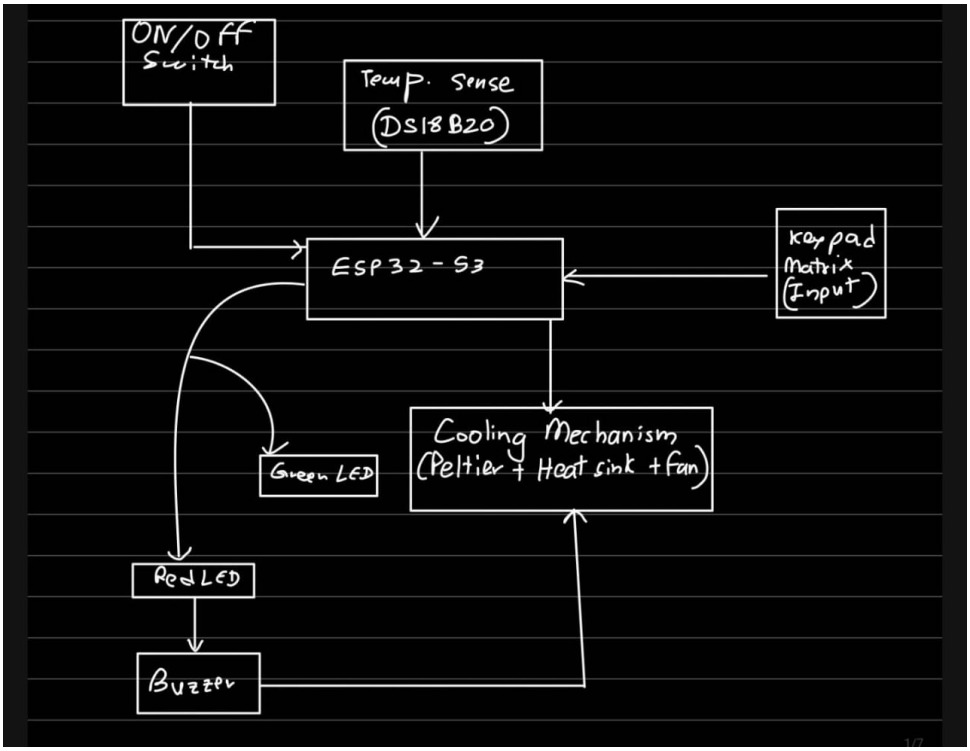

Figure 2: Block diagram of the proposed vaccine carrier prototype

- Cooling performance inside an insulated container at 30–37 °C ambient.
- Alarm responsiveness when thresholds are exceeded.
- Battery runtime and power consumption efficiency.

8 Final Concept Selection

8.1 Killer Risks

- **Temperature Control Failure:** Peltier or fan failure could let temperatures go outside 2–8°C.
- **Power / Battery Failure:** Insufficient battery capacity or charger issues could stop cooling.
- **Sensor / Monitoring Malfunction:** ESP32-S3 could give inaccurate or no readings.
- **Overheating of Electronics:** Hot side of Peltier could damage electronics if heat isn't dissipated properly.
- **Mechanical / Structural Failure:** Poor insulation or enclosure could compromise temperature stability.
- **Regulatory / Compliance Risk:** Failing to meet WHO or local vaccine cold chain standards.
- **Environmental Risks:** Extreme ambient temperature, humidity, or vibration affecting performance.

8.2 Selection Matrix with Ranks and Scores

The selection matrix (Table above) confirms that the **Peltier-based portable vaccine carrier with monitoring and alerts** best balances effectiveness, affordability, and feasibility. With the above subsystem analysis, the feasibility of different concepts for our temperature-controlled vaccine carrier is summarized below. The abbreviations used in the matrix are as follows:

- **IP** - Intellectual Property
- **RR** - Regulatory Requirements
- **RI** - Reimbursement / Cost-effectiveness
- **BM** - Business Model

The objective and concept abbreviations are given below:

- (01) Active Cooling with Peltier + Fan
- (02) Smart Temperature Monitoring + Alerts
- (03) Hybrid: Passive Cooling + Active Peltier

Table 2: Subsystem Analysis for Feasibility Considerations

Subsystem / Concept	IP	RR	RI	BM
Active Cooling (Peltier + Fan)	✓	✓	×	✓
Smart Temperature Monitoring + Alerts	✓	✓	✓	✓
Hybrid: Passive + Peltier	✓	✓	×	✓

Table 3: Weighted Objectives and Concept Screening

Objective	**Weight**	(01)	(02)	(03)
Accuracy (maintain 2–8°C)	5	+1	+1	+1
Portability	3	0	+1	+1
Continuous Monitoring	4	0	+1	0
Affordability	3	0	+1	0
Usability / Ease of Deployment	2	+1	+1	0
Weighted Score	–	7	11	5
Rank	–	2	1	3

9 Conclusion

This report documents the systematic process of concept generation, screening, testing, and selection for a temperature-controlled vaccine carrier. The chosen Peltier-based design offers a promising prototype pathway, addressing the need for safe, affordable, and portable vaccine transport in low-resource settings. Future work will focus on improving cooling efficiency, insulation, and extended battery operation.

References

[1] World Health Organization. *Unit 4: Cold chain and logistics management.* Immunization Handbook. WHO, 2025.

[2] World Health Organization. *Vaccine Management Handbook.* Technical guidance on immunization logistics. Published July 2025.

[3] Centers for Disease Control and Prevention. *Vaccine Storage and Handling Toolkit.* January 2023.

[4] Gilero. *Medical Device Classification - Overview of 3 Classes.* August 2025. Explains FDA Class I, II, III medical devices.

[5] Dallas Semiconductor. *DS18B20 Programmable Resolution 1-Wire Digital Thermometer Datasheet.*

[6] Matsusada Precision. *Thermoelectric Coolers by Peltier.* June 2023. Overview of thermoelectric cooling applications.

10 Appendix

- Appendix A: Brainstorming sketches, notes and concept maps

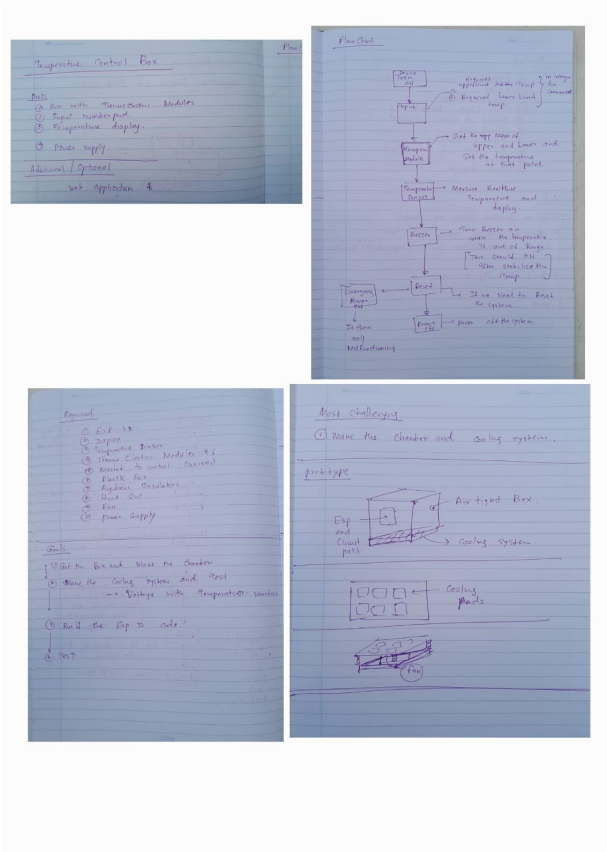

Figure 3: Brainstorm sketches and notes

- Appendix B: Selection matrix with raw scores

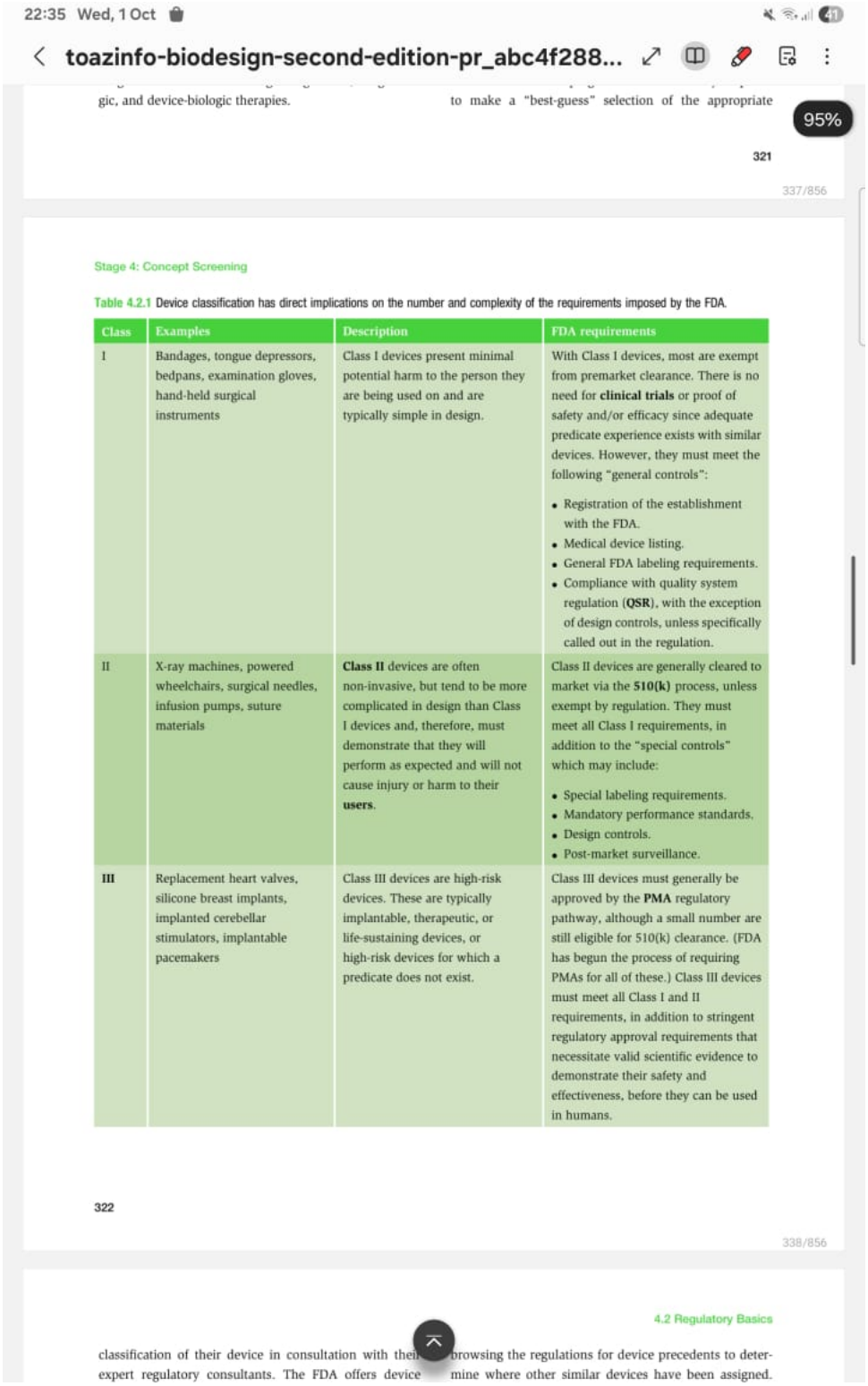

Figure 4: Source : "Biodesign: The Process of Innovating Medical Technologies"