SECTION II – BIO DESIGN INNOVATION PROCESS

1. Bio design innovation process:

Identification

Invention

Implementation

1. Regulatory measures:

Classes of medical devices in USA:

The medical devices are classified into three classes based on the risks in those devices.

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| Class | Level of risk associated with devices. | Description. |
| Class I | Low risk | The failure of medical devices are less complicated and can be easily solved. |
| Class II | More risk than class I | More complicated failure of medical devices occurs. |
| Class III | Higher risk | The risk in the medical devices cause threat to patients and high safety measures has to be taken. |

Classes of medical devices in Europe:

The medical devices are classified into four classes based on Medical device directives (MDD) by considering the risk associated.

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| Class | Level of risk associated with devices | Description |
| Class I | Low risk | The failures in devices can be self-assessed by the manufacturer. |
| Class II a |
| Class II b | High risk | The high risk in device are handled by Notified bodies of EU regulation. |
| Class III |

Classes of medical devices in China:

It includes three classes based on the risk associated with medical devices.

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| Class | Level of risk associated with devices | Description |
| Class I | Low risk | Continuous administration of medical devices has to be done. |
| Class II | More risk | In addition to administration, ensuring the safety of medical devices and their usage has to be included. |
| Class III | Higher risk | Highest safety surveillance for these medical devices is taken. |

Classes of medical devices in India:

It includes four classes based on GHTF(Global Harmonization Task Force).

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| Class | Level of risk associated with devices | Examples of medical devices |
| Class A | Lowest | Stethoscopes, wheel chairs |
| Class B | Low to moderate | Infusion sets |
| Class C | Moderate to High | Ventilators |
| Class D | Highest | Pacemakers |

1. Suggestion to improve Healthcare system in India.

* Making the healthcare facility available to the people of rural area by implementing Mobile healthcare providing facility like telemedicine.
* Increasing the number of healthcare centers in towns and making use of advanced medical devices in hospitals.
* Reduction of fees paid by patients for scanning, and by increasing the fund given by the government to healthcare sector.
* Increasing the fund given to healthcare research and development sector, so that innovation of medical devices, instruments for quick diagnosis of diseases and advancement is possible.
* Instead of prescribing drugs for treatment, finding different methods such as application of Acupressure, acupuncture therapies and applying the traditional methods of treatment and usage of medicinal plants will reduce the cost.
* The percentage of investment of GDP on public healthcare sector should be increased.
* Increasing the number of beds for patients in rural health sectors, especially in Government hospitals will help in keeping the surrounding environment of patient clean and makes them to feel comfortable. If this is followed the possibility of reducing infection is high.
* Frequent inspection in private hospitals to ensure whether the regulation standards have been correctly followed or not. This may reduce the chances of mistakes, errors and may give the surety of their treatment.
* Implementation of Health Insurance schemes, for the benefit of old aged people, and suggesting the government to make the treatment free of cost for physically challenged people.

Block diagram for improving the Healthcare systems in India:

Investing on advanced medical devices

Healthcare Administration

R&D of drugs and medical devices development

Reducing the fees for diagnosis

Development

More number of Hospitals in rural areas

Increasing the facility of telemedicine

Awareness

Innovation in wearable devices

Traditional methods of treatment

More Health insurance schemes