SECTION 2

1. **Biodesign innovation process** is a structured process to develop new medical technologies.

2. All medical devices must satisfy safety and performance, quality system. The degree of regulatory scrutiny increases with the potential risks of the medical device. The device manufacturers should asses the risks. The risk assessment is based on experience, evidence, computation, or even guesswork.

**USA:**

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| **CLASS** | **RISK** | **EXAMPLES** | **SAFETY/EFFECTIVENESS**  **CONTROLS** | **REGULATORY**  **PATHWAY** |
| I | Low | Tongue depressor, hospital beds | **General controls**   * With exemption * Without exemption | **Self-regulation**  Or  **510 (k)** |
| II | Medium | Absorbable suture, Blood pressure cuffs | **General controls**   * With exemption * Without exemption   **Special controls**   * With exemption * Without exemption | * Most class II devices are approved under a **510(k)** pre-market notification submission * Few devices of class II are approved under **PMA** * 10-15 % devices require **clinical trial** |
| III | Highest | Implantable pacemaker, Coronary stent | **General controls**  **Special controls**  **Pre-market authorization** | **Pre-market approval(PMA)**  Almost all require clinical data |

**EUROPE:**

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| **CLASS** | **EXAMPLES** | **REQUIREMENT FOR MARKET CLEARANCE** |
| I | Surgical gauze,  Wheel chair | Self-certifiable  CE marking |
| IIa | Hearing aids,  Ultrasound equipment | Assessment by a notified body |
| IIb | Infusion pump, Surgical lasers | Assessment by a notified body |
| III | Prosthetic joints, Stent-grafts | CE marking |

**INDIA:**

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| **CLASS** | **RISK LEVEL** | **DEVICE EXAMPLES** |
| A | Low risk | Thermometers/Tongue depressors |
| B | Low moderate risk | Hypodermic needles/suction equipments |
| C | Moderate high risk | Lung ventilators/Bone fixation plate |
| D | High risk | Heart valves/Implantable defibrillator |