Review Form 1.7

Journal Name:	**Journal of Engineering Research and Reports**
Manuscript Number:	**Ms_JERR_119393**
Title of the Manuscript:	**Methods for Medical Device Design, Regulatory Compliance and Risk Management**
Type of the Article	**Review Article**

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty'**, provided the manuscript is scientifically robust and technically sound.
To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

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PART 1: Review Comments

	Reviewer's comment	**Author's comment** *(if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)*
Compulsory REVISION comments **1. Is the manuscript important for scientific community?** (Please write few sentences on this manuscript) **2. Is the title of the article suitable?** (If not please suggest an alternative title) **3. Is the abstract of the article comprehensive?** **4. Are subsections and structure of the manuscript appropriate?** **5. Do you think the manuscript is scientifically correct?** **6. Are the references sufficient and recent? If you have suggestion of additional references, please mention in the review form.** **(Apart from above mentioned 6 points, reviewers are free to provide additional suggestions/comments)**	**Risk management encompasses the identification, understanding, control, and prevention of failures that may lead to hazards when medical devices are used. Manufacturers are required to identify potential hazards related to the device design under both normal and fault conditions.** **YES** Despite the evolution of design controls and compliance as essential components in the medical device development process, as mandated by domestic and international regulations and standards, there remains a need for a comprehensive model that outlines the entire approach to medical device design. This gap exists because, while design controls and regulatory compliance are integral to the medical device design process, their integration has not been sufficiently addressed, especially in projects involving complex medical device designs. The medical device sector often prioritizes design controls and regulatory compliance in isolation. However, the integration of these elements has not been adequately considered. This review aims to address the integration of design controls and compliance within the medical device sector. **YES** **YES** **NO, This is sufficient**	
Minor REVISION comments **1. Is language/English quality of the article suitable for scholarly communications?**	YES	
Optional/General comments		

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PART 2:

	Reviewer's comment	**Author's comment** *(if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)*
Are there ethical issues in this manuscript?	*(If yes, Kindly please write down the ethical issues here in details)*	

Reviewer Details:

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